Exhibit 6

Expert Report of Dr. Michael Siegel

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EXPERT REPORT IN

City of Huntington v. AmerisourceBergen Drug Corp. et al., No. 3:17-cv-1362 (S.D.W. Va.); *Cabell County Commission v. AmerisourceBergen Drug Corp. et al.*, No. 3:17-cv-1665 (S.D.W. Va.)

Prepared for:

Plaintiffs' Executive Committee

In Re: National Prescription Opiate Litigation MDL 2804

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I. Background and Qualifications

I, Michael Siegel, MD, MPH, am a physician and a professor of public health in the Department of Community Health Sciences at the Boston University School of Public Health. After graduating from the Yale University School of Medicine with a medical degree, I completed a residency in preventive medicine at the University of California, Berkeley, where I obtained a Master's in Public Health degree with a concentration in epidemiology. I then completed a two-year epidemiology training program at the Centers for Disease Control and Prevention (CDC), where I conducted tobacco research at the Office on Smoking and Health, the nation's lead agency on the issue of smoking and health. For the past 25 years, I have been on the faculty at the Boston University School of Public Health, where I am now a Full Professor in the Department of Community Health Sciences.

Public health is the broad study of the conditions necessary to protect the health of the entire population and the actions necessary to create those conditions. It differs from medical sciences in that while the primary focus of medicine is to treat an individual patient, public health aims to promote health and prevent disease among the entire population. Within public health and epidemiology, there are generally two sub-areas. Infectious disease epidemiology is the study of the impact of infections on the public's health. The epidemiologists who are studying transmission of the COVID-19 virus and the public health experts who are

designing strategies to limit its spread are examples of the infectious disease side of epidemiology and public health. Often overlooked, but equally important, is the other sub-area of public health: chronic disease epidemiology, or the study of non-infectious harms. This represents an incredibly broad spectrum of non-infectious causes of death, including drug use and addiction to substances like alcohol, tobacco, and opioids, injuries from gun violence, and chronic disease related to obesity or to environmental exposure to certain chemicals. My research, teaching, and experience throughout my career has focused on a range of public health issues, primarily in the area of chronic diseases. I bring a specialized perspective, one that looks at a wide range of societal problems from the lens of public health.

The main area of my research has been in the area of substance abuse and addiction, particularly smoking, tobacco use, and alcohol. I have published more than 170 articles in the peer-reviewed literature and many in prestigious journals such as the *New England Journal of Medicine*, *JAMA*, *Annals of Internal Medicine*, the *American Journal of Epidemiology*, and the *American Journal of Public Health*. I have also published in specialty journals in the area of substance use and addiction, including the *American Journal of Alcohol and Drug Abuse*, *Alcohol & Alcoholism*, *Addiction*, *Tobacco Control*, *Nicotine and Tobacco Research*, *Addiction Science and Clinical Practice*, *Substance Use and Misuse*, *Substance Abuse*, and *Alcoholism: Clinical and Experimental Research*. I have also published

a book that discusses strategies for promoting public health to the population. The book, entitled "Marketing Public Health: Strategies to Promote Social Change," is now in its third edition and has been featured as a resource for public health practitioners at the annual conference of the American Public Health Association.

I have testified as an expert witness for plaintiffs in eight different lawsuits against the tobacco industry, including the *Engle*[1] case, in which I was recognized by the court as an expert in the area of addiction. I have also been recognized as an expert in public health, epidemiology, and corporate public health responsibility.

I have experience as a physician in the treatment of addiction in general and in the treatment of opioid addiction specifically. My opioid addiction treatment experience as a practicing physician occurred primarily during the period 1991-1993, when I served as a part-time physician in the methadone program of the Santa Clara County Health Department. I treated several hundred patients for opioid addiction and followed their progress for as long as two years. In my experience, all of the patients (100%) in the methadone program were addicted to opioids and none would have been able to voluntarily stop using opioids cold turkey. It would also have been dangerous for them to do so, since withdrawal from long-term opioid use can result in severe health effects, including death.

[1] *Howard Engle v Philip Morris et al.* Circuit Court of the 11th Judicial Circuit, Dade County FL, General Jurisdiction Division (Case No. 94-08273 CA).

Opioids are unique in that they are one of the few drugs that after chronic use cannot be stopped cold turkey without severe withdrawal and potentially serious adverse health effects.[2]

As an expert in substance use and abuse, the opioid epidemic, the public health duties of pharmaceutical companies and distributors, the role of these companies in the opioid epidemic, and approaches to preventing opioid misuse are all areas that I have covered in my teaching at the Boston University School of Public Health. The opioid epidemic is such a critical public health problem that I have covered it in virtually every semester in the courses that I teach. The School of Public Health has a pharmaceutical program that focuses on the role of pharmaceutical companies in public health. I teach many students in that program, which is another reason I always cover the opioid epidemic in my classes. I have also collaborated with numerous health agencies and organizations that focus on fighting the opioid epidemic, both through my teaching and as a substance abuse expert consultant.

The opinions in this report are based on my overall evaluation of the totality of the evidence regarding the issues upon which I opine. This evidence includes, but is not limited to Defendant documents, published studies, governmental and non-governmental reports and my knowledge of basic principles of public health,

[2] Alcohol and benzodiazepines are also in this category.

biology, chemistry, toxicology and risk analysis. Additionally, I was provided by plaintiff's counsel with an extensive number of documents related to the case, including depositions. A list of these materials I reviewed and/or considered is attached as Appendix A.

I have included citations to some of the key documents upon which my opinions are based, but these documents are not exhaustive of those supporting my opinions. Rather, my opinions are based on the totality of evidence I have reviewed, which includes many more documents than those cited in the body of this report. After reviewing the provided materials for this case, I have formed the following expert opinions, which I hold to a reasonable degree of medical and scientific certainty, and which are based on my training and experience as a physician, epidemiologist, and public health expert using the same type of analyses used in my practice of epidemiology and public health and in composing my published work. These same methodologies have been accepted by numerous other courts in my past expert testimony. I reserve the right to supplement my opinions as new information becomes available. My curriculum vitae detailing my qualifications including a list of my publications, is attached as Appendix B.

Cases in which I have testified are listed on my curriculum vitae. My compensation for this case is $500 per hour of preparation time and deposition time. I am not charging for the actual testimony at trial.

II. Summary of Opinions

Information was available to AmerisourceBergen, Cardinal Health, and McKesson to make them aware that the volume of opioids they were distributing into small communities was inconsistent with public health.

Information was available that oversupply of opioids inconsistent with public health was likely to result in serious, long lasting public health harm.

AmerisourceBergen, Cardinal Health, and McKesson oversupplied these communities, often despite access to information demonstrating that this oversupply was already occurring and was resulting in public health harm.

All three companies continued to oversupply even in the presence of signs of potential misuse and abuse of opioids inconsistent with public health, such as prescriptions from geographically remote doctors.

Information was available to all three companies that abuse of prescription opioids was a burgeoning public health problem and that there was a dramatic increase in the number of opioid overdose deaths.

All three companies continued to oversupply pharmacies in and near Cabell County with opioids, despite available information that oversupply was creating an opioid public health crisis.

Oversupply of opioids in and around Cabell County contributed to and created a public health hazard, with severe, long-lasting adverse public health consequences.

Through their oversupply of opioids, each of these companies substantially contributed to the opioid epidemic in Cabell County, West Virginia and the resulting harms to public health.

III. An Opioid Public Health Epidemic Has Existed and Increased in Cabell County, West Virginia Over the Past Two Decades

There is an opioid epidemic in Cabell County, West Virginia, characterized by massive opioid use, addiction, overdose, and opioid-related deaths. In 2016, the rate of opioid overdose death in Cabell County was 124.0 per 100,000, compared to a rate of 40.6 per 100,000 in the state of West Virginia, and Cabell County had the highest opioid overdose death rate of any county in the state.[3] In fact, in 2016. Cabell County had the second highest opioid overdose death rate of any county in the nation.[4] The rate of opioid prescriptions in Cabell County in 2016 was 1,225 per 1,000.[5] Also in 2016, 12.0% of patients with opioid prescriptions were receiving an average daily dose of more than 90 morphine milligram equivalents

[3] West Virginia Board of Pharmacy. *Prescription Opioid Problematic Prescribing Indicators County Report: Cabell County*. Charleston, WV: West Virginia Department of Health and Human Resources, Bureau for Public Health; October, 2017. Available at https://helpandhopewv.org/docs/PFS_County_Reports/Cabell_PfS%20County%20Reports_Final.pdf.

[4] CDC. CDC WONDER. Multiple Cause of Death Data. Available at https://wonder.cdc.gov/mcd.html.

[5] *Id.*

(MMEs).[6] In the same year, nearly 26% of Cabell County residents had an opioid prescription.[7] The opioid prescription rate in Cabell County in 2016 was 344th out of 2,962 counties in the nation for which the CDC collected data.[8]

The fact that the opioid overdose death rate in Cabell County was three times higher than in the state of West Virginia is particularly notable because in 2014, West Virginia had the highest opioid overdose death rate of any state in the nation (35.5 per 100,000).[9] West Virginia also had the highest opioid overdose death rate of any state in the nation in 2013.[10] In fact, West Virginia led the nation in opioid overdose death rate throughout the period 2010-2018.[11] The age-adjusted drug overdose death rate in West Virginia in 2018 was a striking 51.5 per 100,000, still the highest of any state in the nation.[12] Thus, the opioid epidemic in Cabell

[6] *Id.*

[7] *Id.*

[8] CDC. U.S. County Prescribing Rates, 2016. Available at https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html.

[9] Rudd RA, Aleshire N, Zibbell JE, Gladden RM. Increases in drug and opioid overdose deaths—United States, 2000-2014. *MMWR* 2016; 64(50):1378-1382.

[10] *Id.*

[11] Rudd RA, Seth P, David F. Scholl L. Increase in drug and opioid-involved overdose deaths—United States, 2010-2015. *MMWR* 2016; 65(50-51):1445-1452; CDC. 2018 Overdose deaths. https://www.cdc.gov/drugoverdose/data/statedeaths/drug-overdose-death-2018.html.

[12] CDC. 2018 Overdose deaths. https://www.cdc.gov/drugoverdose/data/statedeaths/drug-overdose-death-2018.html.

County is occurring in the county with the highest overdose death rate in the state that itself has the highest overdose death rate.

The opioid public health epidemic continues in Cabell County and by some measures is getting worse. For example, in 2018, Cabell County had the highest opiate overdose death rate of any county in the nation at 127.1 per 100,000.[13] The opiate overdose death rate in Cabell County increased steadily from 22.9 per 100,000 in 2006, peaking in 2017 at 155.7 per 100,000.[14]

The opioid crisis in the city of Huntington, the largest city within Cabell County, is so severe that on one day in 2016, there were 14 reported opioid overdoses within a five-hour period, prompting a public safety investigation by the CDC.[15]

[13] CDC. CDC WONDER. Multiple Cause of Death Data. Available at https://wonder.cdc.gov/mcd.html.

[14] *Id.*

[15] Massey J, Kilkenny M, Batdorf S, et al. Opioid overdose outbreak—West Virginia, August 2016. *MMWR Morbid Mortal Wkly Rep* 2017;66(37):975-980.

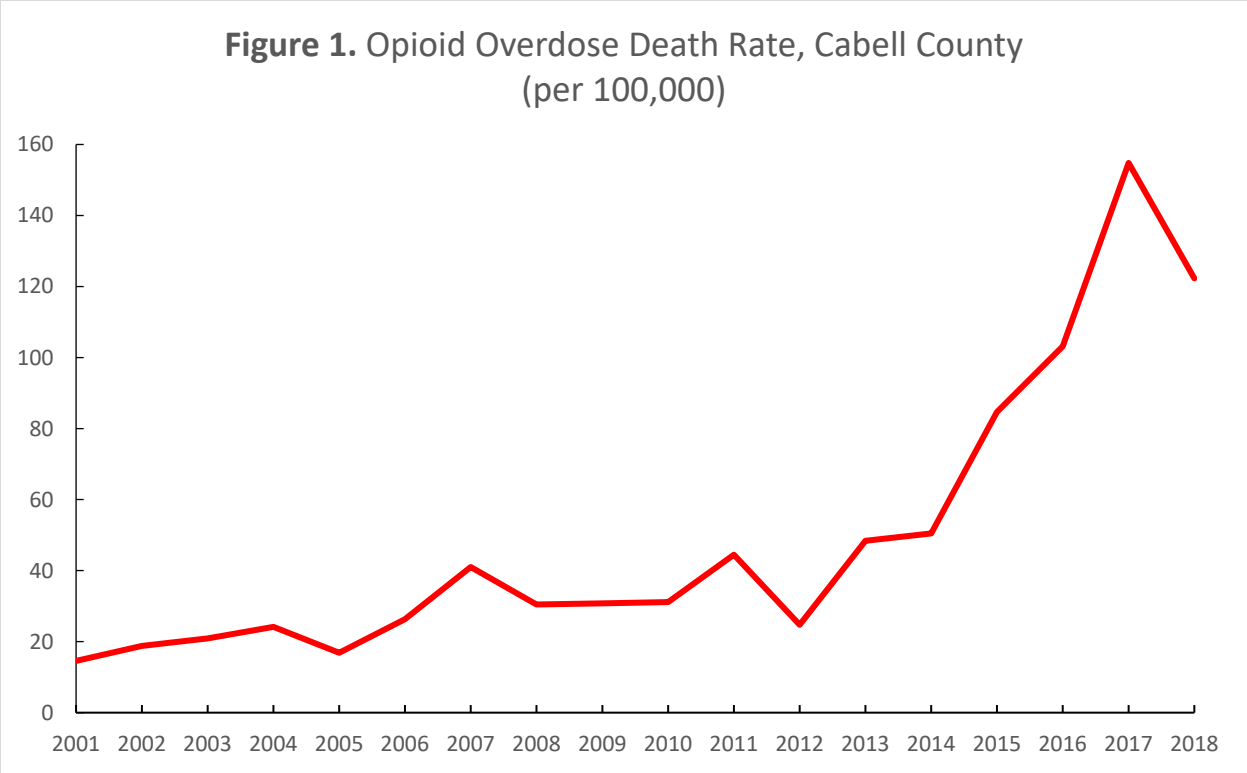

Figure 1 shows the opioid overdose death rate in Cabell County from 2001 through 2018, using data obtained from the CDC WONDER, Multiple Cause of Death database. There is a steady increase in the death rate throughout this period, with a dramatic acceleration in the rate of increase starting in 2012. The rate skyrocketed from 2012 to 2017, before peaking in 2017 and then falling off just slightly in 2018. Despite that small decline, note that the death rate in 2018 was still the second highest recorded in this 18-year period.

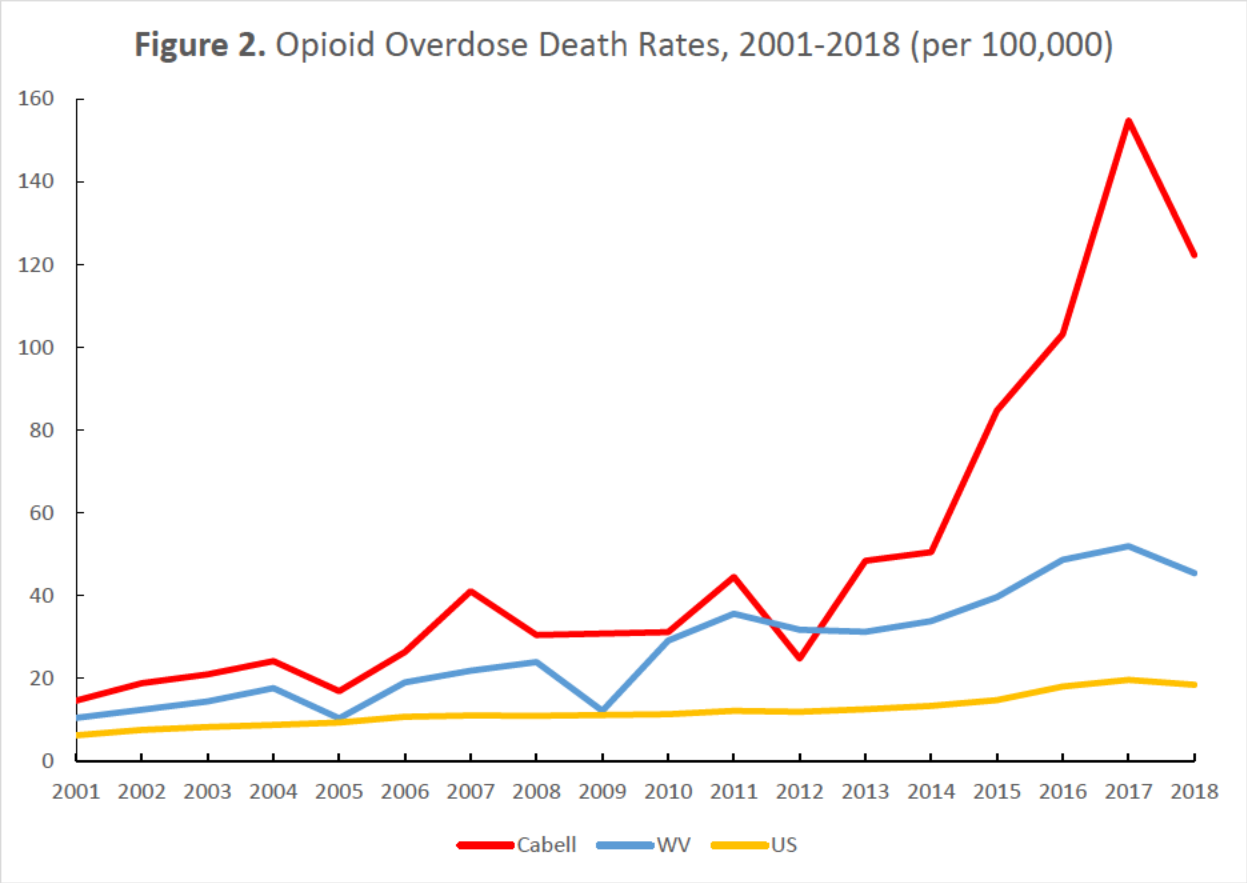

Figure 2 shows the opioid overdose death rate in Cabell County from 2001 through 2018, compared to the rate in West Virginia and in the United States as a whole, using data obtained from the CDC WONDER, Multiple Cause of Death database. While there is a steady increase in the death rate throughout this period in West Virginia, the accelerated rise from 2012 to 2017 is not anywhere near as dramatic as that in Cabell County. The United States as a whole experienced a gradual, but substantial increase in the opioid overdose death rate throughout this time period.

IV. The Oversupply of Prescription Opioid Drugs is a Significant Reason for the Current Opioid Epidemic

It is generally accepted that a significant driver behind the opioid epidemic is the dramatic increase in the volume of opioid drugs being supplied to pharmacies in response to an increase in the writing of opioid prescriptions. A rigorous econometric analysis by Ruhm concluded that increases in opioid supply account for approximately 85% of the observed increase in opioid overdose death rates from 2000-2015.[16] The Centers for Disease Control and Prevention (CDC) reported that the sale of opiate painkillers and the opiate pain reliever overdose death rate rose in parallel from 1999-2008, with the rate of sales quadrupling from 1999-2010 and the opiate pain reliever death rate tripling during roughly the same period.[17] Paulozzi and Ryan showed that there was a significant correlation between states with the highest drug poisoning mortality rates and those with the highest levels of prescription opiate sales in 2002.[18] Modarai et al. demonstrated that there was a correlation between annual opioid sales between 1997 and 2010 and both emergency department overdose visits and unintentional drug deaths in

[16] Ruhm CJ. Deaths of despair or drug problems? NBER Working Paper series. Working paper 24188. Cambridge, MA: National Bureau of Economic Research; January, 2018. Available at https://www.nber.org/papers/w24188.pdf.

[17] Centers for Disease Control and Prevention. Vital signs: overdoses of prescription opioid pain relievers—United States, 1999-2008. *MMWR Morb Mortal Wkly Rep* 2011;60(43):1487-1492.

[18] Paulozzi LJ, Ryan GW. Opioid analgesics and rates of fatal drug poisoning in the United States. *Am J Prev Med* 2006;31(6):506–511.

North Carolina during the same period.[19] Similarly, Piercefield et al. documented a correlation between increases in the rate of opiate prescription and the observed rise in unintentional opiate overdose deaths in Oklahoma during the period 1994-2006.[20] Paulozzi and Stier reported that opioid-related death rates were higher in Pennsylvania than New York in 2006-2007, a period during which the overall distribution of opioid analgesics was approximately two-thirds higher in Pennsylvania.[21] Sims et al. documented that from 1997 to 2004, national prescription rates for methadone increased by 727%, while methadone overdose death rates rose by 1770% during the same period.[22] Grigoras et al. found that the rate of opiate prescriptions based on Medicare Part D data was significantly related to the overall death rate from opiates among 2,710 US counties in a cross-sectional study using combined data from 2013 and 2014.[23]

In an article published in *Pain Medicine* in 2014, Turk—who had received grant support of consulting fees from pharmaceutical companies including

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[19] Modarai F, Mack K, Hicks P, et al. Relationship of opioid prescription sales and overdoses, North Carolina. *Drug Alcohol Depend* 2013;132(1–2):81–86.

[20] Piercefield E, Archer P, Kemp P, Mallonee S. Increase in unintentional medication overdose deaths: Oklahoma, 1994-2006. *Am J Prev Med* 2010;39(4):357-363.

[21] Paulozzi LJ, Stier DD. Prescription drug laws, drug overdoses, and drug sales in New York and Pennsylvania. *J Public Health Policy* 2010;31(4):422-432.

[22] Sims SA, Snow LA, Porucznik CA. Surveillance of methadone-related adverse drug events using multiple public health data sources. *J Biomed Inform* 2007;40(4):382-389.

[23] Grigoras C, Karanika S, Velmahos E, et al. Correlation of opioid mortality with prescriptions and social determinants: A cross-sectional study of Medicare enrollees. *Drugs* 2018;78(1):111-121.

Janssen—and colleagues wrote that: "Corresponding to the rise in opioid prescribing is the expansion in rates of opioid misuse (i.e., inappropriate use of a medication for medical purposes, rather than mind-altering effects), abuse (i.e., use of medication for mind-altering effect or in any manner not consistent with the way in which the opioid was prescribed by the treating physician), as well as both fatal and nonfatal overdoses. … This relationship is more than circumstantial, as multiple investigations have been conducted to support the purported causal influence of increased opioid prescribing to higher rates of misuse, abuse, emergency room visits, and overdose."[24]

Although a substantial proportion of opioid overdoses are due to non-prescription products (e.g., heroin or illicit synthetic opioids), the overwhelming majority of these cases involve individuals who initiated illicit opioid use after developing addiction to prescription opioid drugs, but are no longer able to obtain prescription opioids. Nationally, among all heroin users, nearly 80% report having

[24] Turk DC, Dansie EJ, Wilson HD, Moskovitz B, Kim M. Physicians' beliefs and likelihood of prescribing opioid tamper-resistant formulations for chronic noncancer pain patients. *Pain Medicine* 2014;14:625-636.

started with prescription opioids prior to heroin use.[25,26] People who are addicted to prescription opioid drugs are 40 times more likely to subsequently use heroin.[27]

[25] Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002-2004 and 2008-2010. *Drug Alcohol Depend* 2013;132(1-2):95-100.

[26] Muhuri PK, Gfroerer JC, Davies MC; Substance Abuse and Mental Health Services Administration. Associations of nonmedical pain reliever use and initiation of heroin use in the United States. *CBHSQ Data Review.* Published August 2013.

[27] Jones CM, Logan J, Gladden RM, Bohm MK. Vital signs: demographic and substance use trends among heroin users—United States, 2002–2013. *MMWR Morb Mortal Wkly Rep* 2015;64(26):719–25.

V. Due to the Addictive Nature of Opioid Drugs, All Supply Chain Defendants Had a Public Health Responsibility to Prevent the Oversupply of their Products

Although public health acknowledges individual responsibility in making health-related behavioral decisions, a central feature of public health is the recognition that larger social entities—including corporations—share some responsibility in protecting the public's health.[28] Dr. Nicholas Freudenberg, Distinguished Professor of Public Health at City University of New York School of Public Health, explained this concept as follows: "the way I think about it is that health, and especially public health, is a community responsibility. And yes, individuals have an obligation to protect their health. But corporations also have a responsibility."[29]

Pharmaceutical distributors have a well-recognized public health responsibility to generally and specifically protect the health of the public—to protect the public from the severe health consequences associated with oversupply of drugs. This responsibility derives, in part, from the fact that pharmaceutical distributors are part of the health care industry, whose underlying mission and responsibility is the protection and improvement of the public's health.

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[28] See, for example, Freudenberg N. *Lethal but Legal: Corporations, Consumption, and Protecting Public Health*. Oxford: Oxford University Press; 2014.

[29] Corporate Crime Reporter. Nick Freudenberg on the Corporation, the Individual, and Public Health, July 16, 2019. https://www.corporatecrimereporter.com/news/200/nick-freudenberg-on-the-corporation-the-individual-and-public-health/.

The public health responsibility of pharmaceutical distributors to protect the integrity of the drug supply chain has been articulated by the World Health Organization (WHO). The WHO guidelines state: "All parties involved in the distribution of pharmaceutical products have a responsibility to ensure that the quality of pharmaceutical products and the integrity of the distribution chain is maintained throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient or his or her agent."[30] It is important to note that the WHO refers to this as a *public health responsibility*, and not merely as a *good practice*.

It is also important to note that the responsibility of pharmaceutical distributors goes beyond merely preventing the entry of their products into the illicit market. They also have a responsibility to ensure that the products they sell are being prescribed and used legitimately. The Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services defined drug diversion simply as "the redirection of prescription drugs for illegitimate purposes… ."[31] While those illegitimate purposes may include the resale of drugs

[30] World Health Organization. WHO good distribution practices for pharmaceutical products (Annex 5). WHO Technical Report Series, No. 957, 2010. https://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf?ua=1.

[31] Office of the Inspector General, U.S. Department of Health and Human Services. Spotlight on drug diversion. https://oig.hhs.gov/newsroom/spotlight/2013/diversion.asp.

on the black market, they may also involve supplying drugs for prescriptions that have been inappropriately or illegitimately provided to individuals. As the OIG explains, this may take the form of physicians writing "medically unnecessary" prescriptions, operating "pill mills," and fraudulently billing Medicare or Medicaid for opioid prescriptions, sometimes without examining the patients.[32] Thus, the critical public health responsibility for opioid distributors is to avoid oversupplying pharmacies with quantities of drugs that might indicate either diversion of drugs into the illicit market or to the distribution of illegitimately prescribed drugs through the legal market.

The pharmaceutical companies have readily acknowledged their public health responsibilities and their commitment to carry them out. An article in the May 2007 issue of *PharmaVOICE* states: "The pharmaceutical industry's commitment to public health is at the core of its very existence… ."[33] The same article also asserts that: "The pharmaceutical industry plays an important public-health role just by creating and developing medicines, but it does not stop there."[34] In the article, a senior official at Pfizer states: "We feel our role goes beyond the development, distributing, and selling of medicines and the doctor-patient

[32] *Id.*

[33] Villarroel EP. Going Public: Pharma's Commitment to Health. *PharmaVOICE*, May 2007, p. 10.

[34] *Id.*, p. 14.

interchange; we really believe that as a company we can focus on larger public-health issues. As we introduce our products and programs, we have to introduce other elements that lead to better health. … We are beginning to take a larger worldview of our mission, which is beyond merely the discovery and distribution of medicines and looking at how we fit into the larger health agenda."[35] A senior official at Merck stated: "It is crucial to raise awareness and get the information out there so that people have a very comprehensive view of what we stand for as an organization. The hope is that if they are aware of Merck's commitment to public health it will help to differentiate Merck and raise awareness of the company and lead to all around better feelings about the industry in general."[36]

The public health responsibility to protect public safety has been readily acknowledged by pharmaceutical distributors, individually and through their trade organizations, the Healthcare Distribution Alliance (HDA) and its predecessor, the Healthcare Distribution Management Association (HDMA); yet the Defendant distributors in this case repeatedly and continuously disregarded these obligations, as described below. As demonstrated in the deposition of former HDA President John Gray, the distributors' repeated protestations of public health protection were

[35] *Id.*, p. 18.

[36] *Id.*, p. 21.

more accurately viewed as a form of public relations that veiled their continuous violation of those responsibilities.[37]

In a 2019 report, the HDA wrote that "Pharmaceutical distributors are at the heart of the US health care ecosystem. Distributors handle 92 percent of pharmaceutical sales and add efficiency and order to a supply chain that connects two highly fragmented markets: 1,300 manufacturers and 180,000+ points of dispensation. … Distributors do much more than serve as the intermediary that ships products from manufacturers to pharmacies and providers. … Distributors play a critical role in supporting patient safety, enabling the right product to reach the right patient in a timely and transparent manner, including processing over 200 recall events per year."[38] The HDA describes the responsibility of distributors as "enabling a secure, transparent, and efficient pharmaceutical supply chain that safeguards patient safety… ."[39]

The HDA has acknowledged that the responsibility of distributors to detect and prevent diversion of opioids is not merely a statutory or regulatory responsibility, but that it is also a public health responsibility: "HDMA's members

[37] John Gray Deposition 7/30/2020

[38] HDA and Deloitte. *The Role of Distributors in the US Health Care Industry: 2019 Report*, p. 3. https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-hda-role-of-distributors-in-the-us-health-care-industry.pdf.-

[39] *Id.*, p. 4.

have not only *statutory* and *regulatory* responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as *responsible members of society*. The *public health* dangers associated with the diversion and abuse of controlled prescription drugs have been well-recognized over the years by Congress, the DEA, and *public health* authorities" (emphasis is mine).[40]

The distributors reiterated their understanding that their responsibilities go beyond statutory and regulatory requirements and extend to a responsibility to protect the interests and health of the public (i.e., the public health) in another amicus brief submitted by the HDMA, which stated: "The public health dangers associated with the diversion and abuse of controlled prescription drugs have been well-recognized by Congress, DEA, public health authorities, and others – including HDMA and NACDS and their members. HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[41] This statement also recognizes that the public health responsibility of

[40] Amicus Curiae Brief of Healthcare Distribution Management Association (draft), February 2, 2012. Cardinal Health, Inc. v. Eric H. Holder, Jr., et al. United States District Court for the District of Columbia. Pl.6526. ABDCMDL05782532.

[41] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party. Masters Pharmaceuticals, Inc. v. United States Drug Enforcement Agency. United States Court of Appeals, District of Columbia Circuit, April 4, 2016, p. 5. Exhibit 38 in Hartle deposition.

distributors goes beyond merely preventing diversion into the illicit market but also includes preventing the abuse of opioid drugs in its entirety, which includes the abuse of drugs obtained through the legal market.

The Healthcare Distribution Alliance describes the responsibility of pharmaceutical distributors as "getting the right medicines to the right patients at the right time, safely and efficiently."[42] The HDA goes on to say that "Every day, pharmaceutical distributors sustain a complex supply chain, serving as an important link in the healthcare system and delivering medicines safely, securely and efficiently. As the healthcare system rapidly changes, distributors are constantly envisioning new ways to move and secure the nation's medicines, all while protecting patient safety. … HDA members are not simply distributors. They are technology innovators, information management experts, security specialists and efficiency professionals, whose expertise streamlines the supply chain to reduce costs and save the nation's healthcare system both time and money."[43]

The HDA describes its very first mission as follows: "Protect patient safety and access to medicines through the safe and efficient distribution of healthcare products and services."[44] It also states that one of the central responsibilities of

[42] HDA. Pharmaceutical Distributors: Understanding Our Role in the Supply Chain. https://www.hda.org/about/role-of-distributors. Last accessed June 17, 2020.

[43] *Id.*

[44] HDA. Mission and Values. https://www.hda.org/about/mission-and-values. Accessed June 18, 2020.

distributors is to "continuously monitor, protect and enhance the security of the pharmaceutical supply chain to ensure medicines are properly and securely handled, stored and delivered."[45]

The HDMA also described its mission in similar terms, stating that its primary *responsibility* is the protection of public safety: "The primary responsibility of the healthcare industry is to ensure patient health and safety."[46] The pharmaceutical distributors have also recognized that the public trust is placed upon them to conduct due diligence in protecting public safety: "HDMA members recognize the public trust placed upon them to ensure that authentic pharmaceutical products are handled, stored, and ultimately, dispensed to patients safely and efficiently."[47]

The Healthcare Distribution Management Association explained that exercising due diligence is central to distributors fulfilling their public health obligations in protecting the safety of the drug supply: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of the controlled substances they

[45] HDA. Infographic. https://www.hda.org/~/media/pdfs/communications/2019-01-25-the-vital-link-in-the-pharmaceutical-supply-chain.ashx?la=en.

[46] Gray, JM. Prepared Statement of John M. Gray, president and CEO of the Healthcare Distribution Management Association. *Drug Importation: The Realities of Safety and Security*. Hearing before the Committee on Health, Education, Labor, and Pensions, United States Senate, February 16, 2005, p. 25.

[47] *Id.*

deliver to their customers. Due diligence can provide a greater level of assurance that those who purchase CS [controlled substances] from distributors intend to dispense them for legally acceptable purposes. Such due diligence can reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach."[48]

The pharmaceutical distributors have also explicitly accepted their role in helping to prevent opioid abuse and their commitment to carrying out this role: "HDA and its members are committed to stopping opioid abuse and misuse before it occurs through investments in information technology and state-of-the-art monitoring tools to prevent diversion, initiatives to provide education and awareness to consumers, and practical policy solutions to address opioid abuse and misuse."[49]

One pharmaceutical distributor CEO described the responsibility to make sure that the company distributed opioids only for legitimate purposes as an "imperative," on equal footing with its responsibility to make sure these medications are available for legitimate purposes: "As a distributor, we had to manage the twin *imperatives* of ensuring that we distributed pharmaceuticals appropriately, for legitimate purposes, and ensuring the pharmacies that they had

[48] Healthcare Distribution Management Association (HDMA). Industry Compliance Guidelines. ABDCMDL00000397.

[49] HDA. Pharmaceutical Distributors: Understanding Our Role in the Supply Chain.

the products they needed when the patient arrived with a prescription so as to ensure undisrupted patient care."[50]

Individual distributors have explicitly acknowledged their responsibility to help prevent opioid misuse. This clearly extends to a responsibility not to grossly oversupply pharmacy customers with opioids, as that is a major cause of opioid misuse and addiction. All three of the major distributor Defendants have acknowledged this responsibility:

AmerisourceBergen states as follows: "As an accountable and conscientious healthcare organization, AmerisourceBergen feels it has a responsibility to help address the national issue of opioid misuse."[51] Elsewhere, it reiterates this responsibility: "Employers committed to safe and healthy workplaces have a responsibility to address the opioid epidemic."[52] The company frames its responsibility regarding the opioid crisis within its more general obligations to protect the public's health: "The driving force behind everything we do is our Purpose - we are united in our responsibility to create healthier futures. This

[50] Statement of J. Christopher Smith, former President and CEO, H.D. Smith Wholesale Drug Company, before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, May 8, 2018. *Combating the Opioid Epidemic: Examining Concerns about Distribution and Diversion*, p.41. Pl.6480.

[51] AmerisourceBergen. Fighting the Opioid Epidemic. Frequently Asked Questions. https://www.amerisourcebergen.com/fighting-the-opioid-epidemic/frequently-asked-questions.

[52] AmerisourceBergen. AmerisourceBergen Expands Opioid Assistance Program for Associates, August 22, 2019. https://www.amerisourcebergen.com/newsroom/press-releases/amerisourcebergen-expands-opioid-assistance-program-for-associates. Last accessed June 18, 2020.

Purpose drives every facet of our business and is more important today than ever as we and the country grapple with the opioid crisis. AmerisourceBergen has a longstanding commitment to ensuring a safe and efficient pharmaceutical supply chain. We have taken substantial steps to combat the diversion of controlled substances and fight opioid misuse and abuse. We believe a multifaceted approach, with efforts that stretch across the federal-, local-, and company-level, is imperative to create real change."[53] AmerisourceBergen has expressed its "commitment to the safe handling and distribution of opioids and other controlled substances" and its "ongoing commitment of being an industry leader in diversion control."[54]

Cardinal Health explicitly acknowledges its responsibility to prevent the diversion of opioid medications, stating: "The people of Cardinal Health care deeply about the devastation opioid abuse has caused American families and communities and are committed to being part of the solution. … Our responsibility as a distributor is to provide a safe and secure channel to deliver medications of all kinds, from the hundreds of manufacturers who make them to the thousands of government-authorized pharmacies that fill doctors' prescriptions for patients, and

[53] AmerisourceBergen. Safe and Secure Distribution of Controlled Substances. September, 2019. https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/fighting-the-opioid-epidemic/abc_opioidreport_sept2019.pdf?la=en&hash=2721CF3085BAC3828E639CF6C7FF39B752B9B4DA. Last accessed June 18, 2020.

[54] *Id.*, p. 11.

in that process – within the channels we control – prevent the diversion of pain medications from legitimate and appropriate uses."[55] Cardinal Health describes the prevention of prescription drug diversion and abuse as an "obligation to society": "…our role—and our obligation to society—is to ensure that prescribers, pharmacists and patients have safe, secure and efficient access to the medications they need, when and where they need them while doing our very best to prevent prescription drug diversion and abuse."[56]

McKesson Corporation also explicitly acknowledges its "responsibility" to prevent opioid abuse and stated that it is "fully committed to working with all stakeholders to protect the supply chain and help prevent diversion while ensuring appropriate treatments are available to patients."[57] It has stated that it is "committed to working closely with our partners and customers to fight the opioid abuse epidemic."[58] McKesson has also stated that it is "committed to continuing to make enhancements as needed to ensure our CSMP [Controlled Substances Monitoring Program] remains an effective contribution in our country's battle with

[55] Cardinal Health. Anti-Diversion and Regulation. https://www.cardinalhealth.com/content/dam/corp/web/documents/infographic/cardinal-health-anti-diversion-infographic.pdf. Last accessed June 18, 2020.
[56] Cardinal Health. Dear Colleague letter from George Barrett, 2017. CAH_MDL2804_00112004.

[57] McKesson. Combating the Opioid Abuse Epidemic: A Shared Responsibility that Requires Innovative Solutions. March, 2017.

[58] *Id.*

opioid diversion and abuse."[59] In addition, McKesson has made it clear that it has a responsibility that goes beyond merely its statutory and regulatory duties; that is, that it owes a responsibility to the general public, which is essentially a public health responsibility. In his deposition testimony, Nathan Hartle—McKesson's vice president of regulatory affairs and compliance from 2014—acknowledged (i.e., answered "yes") to the question: "So your answer is, yes, aside from the statutory and regulatory provisions, McKesson acknowledges that it owes a responsibility to the general public to prevent diversion of controlled substances and opium pills into the illicit market?"[60] Later in the deposition, he acknowledged that "aside from your regulatory responsibilities, you also perform a function that serves the public interest at large."[61]

The public health responsibility of the distributor Defendants to protect the integrity of the drug supply system—which they readily acknowledge—aligns with both federal and state statutory requirements.[62] However, it is a widely recognized

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[59] *Id.*

[60] Deposition of Nathan J. Hartle in RE: National Prescription Opiate Litigation. US. District Court for the Northern District of Ohio, Eastern Division, July 31, 2018. Page 85.

[61] *Id.*, pp. 131-132.

[62]Both distributors (all supply chain companies) and dispensers (pharmacies) of opioid drugs are required under federal law to monitor orders for red flags and report suspicious orders to the Drug Enforcement Administration (DEA). Under the federal Controlled Substances Act, distributors and dispensers of controlled substances, including opioids, are required to monitor the orders or prescriptions they receive in order to guard against inappropriate orders and they must report to the DEA if they discover any suspicious orders: "The registrant shall design and operate a system to disclose to the registrant suspicious

principle within the public health field that the public health responsibilities of pharmaceutical distributors are not limited to statutory requirements alone because corporate practices can still potentially harm the public's health and companies have a public health responsibility to avoid harming the public if they are aware that their behavior is likely to result in substantial public health harm.

VI. The Quantities of Opioids Amerisource Bergen, Cardinal Health, and McKesson Corporation Supplied to Pharmacies in and around Cabell County were Inconsistent with Public Health, Particularly Considering Available Information about Opioid Abuse and Harms

A. Methodology

In public health generally and in epidemiology specifically, a common method of assessing whether a local community is facing a particular public health risk and the severity of that public health risk is to compare data at the local level

orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." (21 C.F.R. § 1301.74(b) and 21 C.F.R. § 1301.76(c)) In addition, distributors of opioid drugs are required under West Virginia state law to monitor orders for red flags and report suspicious orders to the state pharmacy board. Under West Virginia's pharmacy rules, all drug distributors must monitor orders and report any suspicious orders to the West Virginia Board of Pharmacy in addition to the DEA: "A wholesale drug distributor shall design and operate a system to disclose to the wholesale drug distributor suspicious orders of controlled substances. A wholesale drug distributor shall inform the Office of the Board of suspicious orders of controlled substances when discovered by the wholesale drug distributor by providing a copy of the information which the wholesale drug distributor provides to the U.S. Drug Enforcement Administration regarding such suspicious orders." (West Virginia Code of State Rules § 15-2-5.3).

to national averages.[63],[64] This concept of evaluating the volume of opioids being supplied to a particular pharmacy in light of the population size for the location of the pharmacy is widely accepted as a means of identifying potential oversupply. In fact, in a May 2015 controlled substances report, McKesson includes this exact analysis as one of the statistics to be examined.[65] The company lists this as a statistic that could raise a public health concern for a particular pharmacy: "The total volume of controlled scripts or overall controlled dispensing is inconsistent with the population size for the location of the customer's business, especially when compared to other pharmacies in the immediate area."[66]

In a 1996 letter to the DEA, Bergen Brunswig Corporation (later AmerisourceBergen) explains that it used precisely the benchmark that I outline above in identifying potential oversupply of individual pharmacies: "By way of background, as you know BBDC participated in the development of a model

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[63] For example, Nesoff et al. evaluated the extent of pedestrian injury in Baltimore and compared these rates to national rates, concluding that there was an over-occurrence of child pedestrian injury because the rate in Baltimore was five times higher than the overall rate nationally Nessof ED, Pollack KM, Knowlton AR, Bowie JV, Gielen AC. Local vs. national: Epidemiology of pedestrian injury in a mid-Atlantic city. Traffic Injury Prevention 2018; 19(4):440-445.

[64] In another study, researchers compared dialysis rates at the local level with the overall national rates in order to identify local hot spots for kidney disease and to assess progress in reducing disease in those hot spots Wakasugi M, Kazama JJ, Narita I. Use of Japanese Society for Dialysis therapy dialysis tables to compare the local and national incidence of dialysis. *Therapeutic Apheresis and Dialysis* 2012; 16(1):63-67.

[65] McKesson. McKesson CSMP "Red Flags." May 2015. Pl.1146. MCKMDL00335740.

[66] *Id.*, p.7.

Excessive Purchase Report now in u.se by many distributor registrants. As used by BBDC, the Excessive Purchase Report lists total customer purchases for the reported month which exceed pre-determined multiples of the average monthly purchases of BBDC's total customers base. The program identifies purchases by individual DEA Drug Code and reads BBDC's sales files to calculate averages to be used as reporting criteria."[67]

Accordingly, to evaluate the volume of opioids distributed into Cabell County I derived a benchmark using the following methodology: generating a national average using ARCOS data compiled by Dr. Craig McCann.[68] The McCann report states that from 2006-2014 there were approximately 114 billion dosage units of oxycodone and hydrocodone distributed in the United States. Using the 2010 Census estimate of 235 million adults in the U.S., this amounts to an average of 0.15 dosage units per day for each adult in the nation. This figure can then be used as a benchmark to assess the volume of opioids distributed into an area of interest – in this instance Cabell County. I use this benchmark to evaluate distributions by individual companies to individual pharmacies by dividing the number of dosage units supplied to the pharmacy per day by the adult population

[67] Letter from Bergen Brunswig Corporation to Drug Enforcement Administration, September 30, 1996. Exhibit 1, Rafalski. ABDCMDL00315791.

[68] Expert Report of Craig J. McCann, PhD, CFA. In Re National Prescription Opiate Litigation: Cabell County and Huntington City WV Case. United States District Court for the Northern District of West Virginia Eastern Division, August 2020

of the municipality in which that pharmacy is located. Using this benchmark to evaluate shipments to a particular pharmacy based on the total number of adults in the municipality in which it is located is extremely conservative because it assumes that each pharmacy supplies the entire city or town.

To validate this benchmark, I looked at a 2011 DEA report that stated the average retail pharmacy in the U.S. dispensed a total of 74,316 dosage units of oxycodone.[69] During the same year, the population of adults in the U.S. was 238 million, and the number of pharmacies was 64,356.[70] This translates into an average across all U.S. pharmacies of 0.055 dosage units of oxycodone per adult per day. Since this only includes oxycodone and not hydrocodone, a benchmark of 0.15 dosage units per day for oxycodone and hydrocodone is reasonable.

Since not every adult takes prescription opioids, the number of dosage units per actual prescription opioid user is going to be much higher than the overall dosage units per adult in the entire population. To account for this, I translated the calculated dosage units per adult per day to an estimate of the dosage units per adult taking prescription opioids per day. From 2006 through 2012, the percentage

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[69] Declaration of Susan Langston. DEA. In the matter of Cardinal Health. Docket No. 12-32, April 13, 2012. Pl. 4207. CAH_MDL_PRIORPROD_DEA12_00004166

[70] Qato DM, Zenk S, Wilder J, Harrington R, Gaskin D, Alexander GC. The availability of pharmacies in the United States: 2007-2015. *PLoS ONE* 2017;12(8):e0183172. https://doi.org/10.1571/journal.pone.0183172

of adults aged 20 and over who used a prescription opioid analgesic in the past 30 days was 6.9%.[71] I use this value of 6.9% throughout the report in order to translate the dosage units per all adults in the population to estimated dosage units per prescription opioid taking adult. This figure is consistent with other who have made a similar evaluation.[72],[73]

The estimate of 6.9% of adults taking prescription opioid medication is conservative because it is the highest reported usage of any year in the past two decades. For example, the National Center for Health Statistics (NCHS) at CDC estimated that between 2015 and 2018, 5.7% of adults ages 20 and older in the

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[71] Frenk SM, Porter KS, Paulozzi LJ. Prescription opioid analgesic use among adults: United States, 1999-2012. *NCHS Data Brief* (No. 189). National Center for Health Statistics, Centers for Disease Control and Prevention; February 2015.

[72] Beyond CDC's estimates, there was at least one private effort to estimate the prevalence of adult prescription opioid use in the United States. Researchers from Boston University's Slone Epidemiology Center used a random-digit-dial telephone survey to generate an estimate of the national prevalence of prescription opioid use over the period 1999-2007 They reported that 2.0% of adults used prescription opioids regularly (at least 20 days in the year), while an additional 2.9% used prescription opioids less frequently. Thus, their overall estimate of the prevalence of adult prescription opioid use in the U.S. was 4.9%, which is considerably lower than the 6.9% figure I am using. Kelly JP, Cook SF, Kaufman DW, Anderson T, Rosenberg L, Mitchell AA. Prevalence and characteristics of opioid use in the US adult population. *Pain* 2008; 138:507-513.

[73] Hauser et al. reported that between 2007 and 2009, the average opioid consumption per person in the U.S. was 39,487 dosage units per person per day. Converting this to a figure per adult, it amounts to approximately 0.05 dosage units per adult per day. Since opioid consumption was at its peak around 2012 (and was 30% higher in that year than in 2007-2009), the most conservative figure resulting from this data is a benchmark of .07 dosage units per person per day. This is half of the benchmark of 0.15 that I am using, again showing that my benchmark is quite conservative. Hauser W, et al. The opioid epidemic and the long-term opioid therapy for chronic noncancer pain revisited: a transatlantic perspective. *Pain Management* 2016; 6(3):249-63.

U.S. had used prescription opioids in the past 30 days.[74] The NCHS also estimated that between 2013 and 2016, the proportion of adults ages 20 and over who reported using a prescription opioid in the past 30 days was 6.5%.[75]

The estimate of 6.9% is also conservative because it includes all opioids and not just oxycodone and hydrocodone and because it includes all adults who reported using opioid pain medications in the past month, even if that use were simply for acute pain.[76]

[74] Hales CM, Martin, CB, Gu Q. Prevalence of prescription pain medication use among adults: United States, 2015-2018. NCHS Data Brief. No. 369. June 2020. Hyattsville, MD: National Center for Health Statistics, Centers for Disease Control and Prevention; June 2020. https://www.cdc.gov/nchs/data/databriefs/db369-h.pdf

[75] Frenk SM, Gu Q, Bohm MK. Prevalence of prescription opioid analgesic use among adults: United States, 2013-2016. Bethesda, MD: National Center for Health Statistics, Centers for Disease Control and Prevention; December 2019. https://pdfs.semanticscholar.org/1ecb/131ae0143811eda5407e90711dfb9e876b22.pdf.

[76] There has been at least one attempt to measure the prevalence of adult use of opioid use for chronic treatment of noncancer pain. Campbell et al. studied a population of Kaiser Permanente patients in northern California. Among men ages 18-44, the prevalence of opioid use for chronic treatment of noncancer pain in 2005 was approximately 1.5%. Among men ages 45-64, it was approximately 4.0%. Among men ages 65+, it was 5.4%. Among women ages 18-44, the prevalence of opioid use for chronic treatment of noncancer pain in 2005 was approximately 2.0%. Among women ages 45-64, it was approximately 5.3%. Among women ages 65+, it was 8.9%. Based on the age-sex population distribution in California, the estimate for the overall prevalence of prescription opioid use for noncancer chronic pain is approximately 3.3%. This suggests, again, that 6.9% is a conservative figure for the proportion of adults who chronically take prescription opioids. The same article provided similar estimates for patients of the Group Health Cooperative in Washington State, and all of these estimates were lower than the corresponding estimates for Kaiser Permanente. Campbell CI, Weisner C, LeResche L, et al. Age and gender trends in long-term opioid analgesic use for noncancer pain. American Journal of Public Health 2010; 100:2541-2547. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2978198/pdf/2541.pdf.

Based on these estimates, the 0.15 dosage units per adult per day in the overall population translates into a benchmark of 2.2 dosage units per prescription opioid taking adult.[77]

To summarize, based on the average amounts of oxycodone and hydrocodone being distributed nationally in the U.S. during the period 2006-2014, conservative benchmarks to evaluate possible oversupply of particular pharmacies are:

- 0.15 dosage units per adult per day; and
- 2.2 dosage units per prescription opioid taking adult per day.

B. AmerisourceBergen

1. AmerisourceBergen supplied pharmacies in Cabell County with quantities of opioids that were inconsistent with Public Health.

AmerisourceBergen shipped large quantities of opioids to Cabell County and the City of Huntington that were inconsistent with public health at a time when information linking excessive supply of opioids to negative public health

[77] As a check on the benchmark of 2.2 dosage units per adult oxycodone or hydrocodone user per day, I divided the total average dosage units of oxycodone and hydrocodone during the period 2006-2014 (from the McCann report) by the estimated number of past-month users of prescription opioids during that period (from Frenk et al., 2015). The average annual total distribution of oxycodone and hydrocodone in the U.S. during the period 2006-2014 was 12.67 billion dosage units. With an estimated average adult population of 235 million (U.S. Census, 2010) and an estimated 6.9% being past-month opioid users (16.2 million), the average number of dosage units of oxycodone and hydrocodone per adult prescription opioid user per day during this time period comes to 2.14. Thus, a benchmark of 2.2 dosage units per adult prescription opioid user per day appears to accurately reflect the average distribution over the U.S. during this time period.

consequences was available.[78] Here, and throughout, I refer to excessive supply of opioids in a manner inconsistent with public health as "oversupply." For example, AmerisourceBergen oversupplied opioids to Fruth Pharmacy #5 in Milton, West Virginia, a town with a population of just 2,423 people and 1,926 adults (2010 Census). Between 2005 and 2009, AmerisourceBergen supplied Fruth Pharmacy #5 with 2.7 million dosage units of oxycodone and hydrocodone (Table 1). This is enough to provide every adult in Milton with 0.78 dosage units of opioids every day of the year, which is more than 5 times higher than the benchmark of 0.15. This translates into 11.3 dosage units per prescription opioid taking adult per day, far exceeding the benchmark of 1.9 and representing a level of opioid distribution that is inconsistent with public health. There is no way that every prescription opioid taking adult in Milton could be taking 11 pills per day in a way that is consistent with public health.

[78] My conclusions regarding the quantity of opioids supplied to pharmacies in West Virginia are based on ARCOS data. While I have chosen to highlight eight specific pharmacies in this discussion, I have reviewed the data related to all pharmacies supplied by AmerisourceBergen, Cardinal Health and McKesson in Cabell County, West Virginia. In addition to publicly available ARCOS data, plaintiff's attorneys made available ARCOS data that were summarized in the expert report of Dr. Craig McCann (Expert Report of Craig J. McCann, PhD, CFA. In Re National Prescription Opiate Litigation: Cabell County and Huntington City WV Case. United States District Court for the Northern District of West Virginia Eastern Division, August 2020).

Table 1. AmerisourceBergen Shipments to Fruth Pharmacy #5 in Milton, West Virginia (dosage units)

Year	Oxycodone	Hydrocodone	Total	Average dosage units per adult per day*	Times higher than benchmark	Average dosage units per estimated number prescription opioid taking adults, per day**
2005	88,100	396,700	484,800	0.69	5.2	10.0
2006	112,500	385,400	497,900	0.71	4.7	10.3
2007	123,800	440,300	564,100	0.80	5.3	11.6
2008	158,600	437,800	596,400	0.85	5.7	12.3
2009	158,300	426,960	585,260	0.83	5.5	12.1
2005-2009	**641,300**	**2,087,160**	**2,728,460**	**0.78**	**5.2**	**11.3**

*Dosage units per all adults in the population.

**Assumes 6.9% of adults in Milton were taking prescribed opioid medication, which is the percentage of adults nationally who, in 2006-2012, reported using a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

In one month alone (June 2006), AmerisourceBergen supplied Fruth Pharmacy #5 with 101,000 dosage units of oxycodone and hydrocodone, which is a whopping 25.0 dosage units per prescription opioid taking adult per day (Table 2). Stated another way, in June 2006, Amerisource Bergen supplied Fruth Pharmacy #5 with enough oxycodone and hydrocodone so that every prescription opioid taking adult in Milton could take 25 opioid pills per day. This is more than 11 times higher than the benchmark. While the volumes of oxycodone and hydrocodone were lower the following June, the amount was still enough to supply every prescription opioid taking adult in Milton with 11 dosage units per day.

Table 2. AmerisourceBergen Shipments to Fruth Pharmacy #5 in Milton, West Virginia (dosage units)

Month/Year	**Oxycodone and Hydrocodone Total**	**Dosage units per adult per day***	**Times higher than benchmark (dosage units per adult per day)**	**Dosage units per estimated number prescription opioid taking adults per day****
June 2006	101,000	1.72	11.5	25.0
June 2007	44,600	0.76	5.1	11.0

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Milton were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

In 2008, AmerisourceBergen oversupplied The Medicine Chest in Lesage, West Virginia, a town with a population of just 1,358 people and 1,073 adults (2010 Census), with prescription opioids. AmerisourceBergen oversupplied The Medicine Chest continuously throughout the period 2006-2008 with an amount of oxycodone and hydrocodone which steadily increased from the equivalent of 3.3 to 4.5 dosage units per prescription opioid taking adult per day (Table 3).

Table 3. AmerisourceBergen Shipments to The Medicine Chest in Lesage, West Virginia (dosage units)

Year	Oxycodone	Hydrocodone	Total	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2006	17,800	71,300	89,100	0.23	1.5	3.3
2007	22,000	83,800	105,800	0.27	1.8	3.9
2008	20,500	99,800	120,300	0.31	2.1	4.5

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Lesage were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

Beyond consideration of individual pharmacies, the total amount of oxycodone and hydrocodone being distributed by AmerisourceBergen into Cabell County was also inconsistent with public health. For example, in 2009, the monthly distribution of oxycodone by AmerisourceBergen in Cabell County was as high as 182,660 dosage units (August), and the monthly distribution of hydrocodone was as high as 349,200 dosage units (December) (Table 4). The combined oxycodone and hydrocodone distribution was as high as 529,360 dosage units in December 2009. With an adult population of 77,344 (2010 Census), this translates into 0.23 dosage units per adult per day, or 3.3 dosage units per prescription opioid taking adult per day. This volume of opioid supply alone is inconsistent with public health.

Moreover, AmerisourceBergen was not the only supplier of oxycodone and hydrocodone into Cabell County. That other distributors were also supplying opioids into Cabell County during this time was information available to AmerisourceBergen.

Table 4. Approximate AmerisourceBergen Shipments to Cabell County, West Virginia (dosage units)

Year	Oxycodone	Hydrocodone	Total	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
August 2009	182,660	311,500	494,160	0.21	1.4	3.0
December 2009	180,160	349,200	529,360	0.23	1.5	3.3

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Cabell County were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

Overall, the volume of opioids supplied by AmerisourceBergen to Cabell County and the City of Huntington during the entire period 2006-2014 was the equivalent of 5-7 dosage units per prescription opioid taking adult per day, after accounting for the company's share of the oxycodone and hydrocodone market (Table 5).

Table 5. AmerisourceBergen Shipments to Cabell County and Huntington, West Virginia

Year	Dosage units (oxycodone and hydrocodone)	Population	Adults	Doses/ adult/ day*	Doses per estimated number of prescription opioid taking adults per day**	Company market share in Cabell County	Adjusted dose/ estimated number of prescription opioid taking adults/ day
2006	4,735,720	98,955	79,461	0.16	2.3	0.43	5.3
2007	5,201,780	99,054	79,540	0.18	2.6	0.41	6.3
2008	5,317,210	99,190	79,650	0.18	2.6	0.39	6.7
2009	5,892,900	99,991	80,293	0.20	2.9	0.43	6.7
2010	3,748,660	100,270	80,517	0.13	1.9	0.30	6.3
2011	3,785,260	100,380	80,605	0.13	1.9	0.30	6.3
2012	3,016,080	100,658	80,828	0.10	1.5	0.26	5.8
2013	2,584,790	100,717	80,876	0.09	1.4	0.24	5.8
2014	3,081,200	100,299	80,540	0.10	1.5	0.27	5.6

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Cabell County were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

Market share data was available to opioid distributors. This data was sufficient to inform an understanding of their individual market share in the area in order to ensure their own sales volume and opioid supply was consistent with public health. There were databases available from which that information could have been obtained. For example, Walker et al. explain that: "The IQVIA Longitudinal Prescription ("LRx") database as used for this study had information on 234 million patients and in 2013 covered 86% of all retail dispensing in the US. LRx data are assembled and continuously updated to facilitate one of IQVIA's business lines as a clearinghouse for drugs payment information. LRx includes prescription fill data from pharmacy chains, food stores, mass merchandisers,

independent stores and long-term care facilities across the US. From each of the outlets, the database captured all fills, both in person and through the mail, both paid by insurance and paid entirely by the consumer."[79] Similarly, McDonald and Carlson used data from IMS Health in 2008 to obtain data on opioid prescriptions at the pharmacy level within U.S. counties.[80]

In fact, AmerisourceBergen did contract with IMS Health to access prescription data from a wide variety of databases, including those which provide localized market share data on controlled substances sales, indicating its own market share for hydrocodone and oxycodone in various geographic areas was available information.[81] It appears that AmerisourceBergen maintained this data agreement between 2012 and 2019, which allowed it to have access to prescription sales data for other companies.[82] The contract with IMS Health dates back to at least January 1, 2003.[83]

[79] Walker AM, Weatherby LB, Cepeda MS, Bradford DC. Information on doctor and pharmacy shopping for opioids adds little to the identification of presumptive opioid abuse disorders in health insurance claims data. *Substance Abuse and Rehabilitation* 2019; 10:47-55.

[80] McDonald DC, Carlson KE. The ecology of prescription opioid abuse in the USA: geographic variation in patients' use of multiple prescribers ("doctor shopping"). *Pharmacoepidemiology and Drug Safety* 2014; 23(12):1258-1267.

[81] IMS Health. Fourth amendment to data agreements and fourth amendment of information services agreement. Pl.6527. ABDCMDL00375381.

[82] IMS Health. Second amendment to information services agreement. Pl.6528. ABDCMDL00375395.

[83] IMS Health. Information Services Agreement, January 1, 2003. Pl.6529. ABDCMDL00375401.

2. AmerisourceBergen oversupplied a pharmacy in a nearby county in West Virginia with opioid drugs.

In 2010, Oceana, West Virginia—located in Wyoming County—had a population of 1,394 and an adult population of 1,101. In 2011, AmerisourceBergen began to supply opioids to Westside Pharmacy in Oceana. The records from this pharmacy for the prior year show that Westside Pharmacy received 663,200 dosage units of oxycodone and 439,100 dosage units of hydrocodone, or a total of 1,102,300 dosage units of the two drugs combined.[84] This supply of opioids equates to 2.74 doses per adult per day, which is 18 times higher than the benchmark of 0.15. It is the equivalent of nearly 40 doses of hydrocodone and oxycodone per prescription opioid taking adult per day, based on an estimate of a 6.9% prescription opioid taking adults in the town (Table 6). Opioid supply at this level indicates a number of opioids being shipped to, and presumably dispensed by, that pharmacy that is inconsistent with public health.

[84] Opioid Shipments to Pharmacies in Wyoming County, WV, 2006-2014. Pl.6384.

Table 6. Total Shipments to Westside Pharmacy in Oceana, West Virginia in 2010 (dosage units)

Year	Oxycodone	Hydrocodone	Total	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2010	663,200	439,110	1,102,300	2.74	18.3	39.8

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Oceana were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

As part of application process for Westside Pharmacy in 2011, information was available to AmerisourceBergen that a number of "pain doctors" were ordering prescriptions at Westside Pharmacy.[85] One of these doctors was located one hour away in Daniels, WV (Dr. Michael Kostenko); another was located one hour away in Beckley, WV (Dr. John Pellegrini); a third was located one hour 40 minutes away in Charleston, WV (Dr. Iraj Derakhshan); a fourth was located two hours away in Pembroke, VA (Dr. David Morgan); and a fifth had an address in Washington, DC, which is five and a half hours away from Oceana (Dr. Alen Salerian). Only one of the physicians on the list was located in Oceana. From a public health perspective, observing that pharmacies are filling opioid prescriptions

[85] AmerisourceBergen. Westside Pharmacy Pain Doctors. Pl.6281 ABDCMDL00003803

from physicians located hours away is an indication of drug misuse.[86] In fact, all five of these doctors were subsequently investigated for, indicted for, or convicted of criminal charges regarding their opioid prescribing.[87] Supplying opioids to fill prescriptions from geographically remote pain doctors is inconsistent with public health.

Despite the available information regarding the public health implications of Westside Pharmacy's opioid supply, AmerisourceBergen nevertheless began to supply opioids to Westside Pharmacy, with large volumes of opioid medication being supplied in 2011 and 2012 (Table 7).

Table 7. AmerisourceBergen Shipments to Westside Pharmacy in Oceana, West Virginia (dosage units)

Year	Oxycodone	Hydrocodone	Total	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2011	207,100	94,000	301,100	0.75	5.0	10.9
2012	261,600	63,600	325,200	0.81	5.4	11.7

[86] House Energy and Commerce Committee. *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*. Washington, DC: U.S. House of Representatives, Energy and Commerce Committee, December 19, 2018.

[87] *OxyContin: Its Use and Abuse*. Hearing before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, August 28, 2001, p. 160. Also: (Salerian), Beckley Area Physician Sentenced to 20 Years in Federal Prison for Oxycodone Crime, Pl.6143 and WV Allows Painkiller Addicts to Sue Prescribing Doctors, Pl.6159 (Kostenko), Former Giles County Doctor, Stripped of License, Faces Federal Criminal Probe, Pl.6145 and Before The Board of Medicine David Lee Morgan, Pl.6147 (Morgan), Hope Clinic Doctor Pellegrini Pleads Guilty in Drug Case, Pl.6146 (Pellegrini), and Charleston Doctor Pleads Guilty to Federal Crime Involving Dispensing Fentanyl,Pl.6144 (Devakhshan).

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Oceana were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

In 2011, AmerisourceBergen supplied Westside Pharmacy with 0.75 dosage units per adult per day, which is 5 times higher than the benchmark and enough to supply every prescription opioid taking adult in Oceana with 11 doses per day (Table 7). In 2012, AmerisourceBergen supplied Westside Pharmacy with 0.81 dosage units per adult per day, which equates to nearly 12 dosage units per prescription opioid taking adult per day. These numbers are even more troublesome from a public health perspective because Westside Pharmacy was only one of three pharmacies in Oceana and because AmerisourceBergen was only one of several companies supplying opioid drugs to Westside Pharmacy.

Although AmerisourceBergen ceased distributing to Westside Pharmacy in 2012, it approved the same pharmacy with the same pharmacist as a new customer again in 2016, despite the fact that in its application, the pharmacy listed three of its top five prescribing physicians who were located more than one hour away (Dr. David Morgan in Pembroke, VA: two hours away, Dr. Michael Kostenko in Daniels, WV: one hour away; and Dr. Sanjay Mehta in Beckley: one hour away).[88] As noted above, from a public health perspective, observing that pharmacies are

[88] AmerisourceBergen. Customer due diligence materials: Westside Pharmacy. Pl.6164. ABDCMDL00004150.

filling opioid prescriptions from physicians located hours away is an indication that drug misuse is occurring.[89] Moreover, one of these physicians (the top prescribing physician) was Dr. David Morgan, was discussed as being a potential concern in AmerisourceBergen's commissioned compliance report of February 15, 2015, which stated that "Dr. David Morgan, DO wrote for 1,852 oxycodone prescriptions and 212 Oxycontin prescriptions in 2012" and that "Dr. Morgan currently has a case pending with the Virginia Board of Medicine."[90] In 2014, the Virginia Board of Medicine had specifically alleged that Dr. Morgan violated state controlled substances regulations by inappropriately prescribing opioid medications to multiple patients and issued him a reprimand.[91]

At the time Westside Pharmacy's submitted its reapplication to AmerisourceBergen for opioid supply in 2015, information was available showing that this pharmacy—located in a town of population of only 1,100 adults—was dispensing or requesting to dispense 35,000 dosage units of oxycodone and 22,000 dosage units of hydrocodone per month (Table 8).[92] This is the equivalent of 1.4

[89] House Energy and Commerce Committee. *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*. Washington, DC: U.S. House of Representatives, Energy and Commerce Committee, December 19, 2018.

[90] Sullivan, EM. Observations and Recommendations Report: Beckley Pharmacy. Milford, MA: The Pharma Compliance Group, February 15, 2015. Pl.6162. ABDCMDL00003780.

[91] Pl.6164. ABDCMDL00004150

[92] AmerisourceBergen. Customer due diligence materials: Westside Pharmacy, December 2015. Pl. 6457. EC_ABDC_00000371.

doses per adult per day, which amounts to more than 20 dosage units per prescription opioid taking adult per day. Supplying that volume of opioids is inconsistent with public health.

Table 8. Reported Monthly Usage of Oxycodone and Hydrocodone by Westside Pharmacy in Oceana, West Virginia in its December, 2015 re-application to become a customer of Amerisource Bergen (dosage units)

Oxycodone	**Hydrocodone**	**Total**	**Dosage units per adult per day***	**Times higher than benchmark**	**Dosage units per estimated number of prescription opioid taking adults per day****
35,000	22,000	47,000	1.4	9.3	20.3

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Oceana were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

AmerisourceBergen approved the Westside Pharmacy application and, in 2016, shipped [redacted] dosage units of oxycodone and hydrocodone, enough to supply every prescription opioid taking adult in the town with 12 dosages per day (Table 9). In 2017, AmerisourceBergen was still distributing the equivalent of nearly 5 doses per prescription opioid taking adult per day into this small town.

Table 9. AmerisourceBergen Shipments to Westside Pharmacy in Oceana, West Virginia (dosage units)

Year	Oxycodone	Hydrocodone	Total	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2016	[redacted]	[redacted]	[redacted]	0.85	5.7	12.3
2017	[redacted]	[redacted]	[redacted]	0.32	2.1	4.7

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Oceana were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

C. Cardinal Health

1. Cardinal Health supplied pharmacies in Cabell County with quantities of opioids that were inconsistent with Public Health.

Cardinal Health shipped large quantities of opioids to Cabell County and the City of Huntington that were inconsistent with public health at a time when information that linking excessive supply of opioids to negative public health consequences was available. In particular, Cardinal Health oversupplied Fruth Pharmacy #5 in Milton, West Virginia, a town with a population of just 2,423 people and 1,926 adults (2010 Census). Between 2010 and 2017, Cardinal Health supplied Fruth Pharmacy #5 with [redacted] of oxycodone and hydrocodone (Table 10).

Table 10. Cardinal Health Shipments to Fruth Pharmacy #5 in Milton, West Virginia (dosage units)

Year	Oxycodone	Hydrocodone	Total	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2010	100,660	362,920	463,580	0.66	4.4	9.6
2011	84,300	336,450	420,750	0.60	4.0	8.7
2012	91,600	280,400	372,000	0.53	3.5	7.7
2013	98,000	265,600	363,600	0.52	3.5	7.5
2014	112,000	223,100	335,100	0.48	3.2	6.9
[redacted]						

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Milton were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

During the period 2010-2017, Cardinal Health supplied Fruth Pharmacy #5 with enough oxycodone and hydrocodone to supply every prescription opioid taking adult with an estimated average of [redacted] per day throughout this entire period (Table 10). On average during this period, the volume of opioids supplied to this pharmacy was more than 3 times higher than the benchmark of 0.15 dosage units per adult per day.

Also, in 2017, Cardinal Health oversupplied CVS Pharmacy #10566 in Milton, West Virginia, a town with a population of just 2,423 people and 1,926 adults (2010 Census). During that year, Cardinal Health supplied CVS Pharmacy

[redacted] of oxycodone and hydrocodone, which is the equivalent of [redacted] per prescription opioid taking adult per day (Table 11). Cardinal Health had already oversupplied this same pharmacy with a similar amount of oxycodone and hydrocodone in 2016.

Table 11. Cardinal Health Shipments to CVS Pharmacy #10566 in Milton, West Virginia (dosage units)

Year	Oxycodone	Hydrocodone	Total	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Milton were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

Overall, the volume of opioids being supplied by Cardinal Health to Cabell County and City of Huntington during the entire period 2006-2014 amounted to between 5.2 and 7.6 dosage units per prescription opioid taking adult per day, after accounting for the company's share of the oxycodone and hydrocodone market (Table 12).

Table 12. Cardinal Health Shipments to Cabell County and Huntington, West Virginia

Year	Dosage units (oxycodone and hydrocodone)	Population	Adults	Doses/ adult/ day*	Doses per estimated number of prescription opioid taking adults per day**	Company market share in Cabell County	Adjusted doses per prescription opioid taking adult per day*
2006	1,119,900	98,955	79,461	0.04	0.6	0.10	6.0
2007	1,058,640	99,054	79,540	0.04	0.6	0.08	7.5
2008	1,219,320	99,190	79,650	0.04	0.6	0.08	7.6
2009	1,283,680	99,991	80,293	0.04	0.6	0.09	6.7
2010	3,202,130	100,270	80,517	0.11	1.6	0.25	6.4
2011	2,800,840	100,380	80,605	0.10	1.5	0.22	6.8
2012	2,821,370	100,658	80,828	0.10	1.5	0.24	6.2
2013	2,636,450	100,717	80,876	0.09	1.3	0.25	5.2
2014	2,664,490	100,299	80,540	0.09	1.3	0.23	5.7

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Cabell County were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

2. Cardinal Health oversupplied pharmacies in nearby counties in West Virginia with opioid drugs.

Between 2006 and 2014, Cardinal Health distributed 3,973,530 dosage units of hydrocodone and oxycodone to the Hurley Drug Company pharmacy in Williamson, West Virginia,[93] which had an adult population in the 2010 Census of 2,731 (Table 13). This means that during this nine-year period, Cardinal supplied the equivalent of 0.44 dosage units of opioids per day to every adult in the town. This is the equivalent of 6.4 dosage units per prescription opioid taking adult per

[93] House Energy and Commerce Committee. *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*. Washington, DC: U.S. House of Representatives, Energy and Commerce Committee, December 19, 2018.

day, without even taking into consideration the distribution of opioid drugs by any other company. This volume of distribution is inconsistent with public health in the areas, especially since there was another pharmacy four blocks away in the same town.[94]

Table 13. Cardinal Health Shipments to Hurley Drug Company in Williamson, West Virginia (dosage units)

Year	Oxycodone and Hydrocodone	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2006-2014	3,973,530	0.44	2.9	6.4

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Williamson were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

In 2006 alone, Cardinal Health distributed 807,000 dosage units of opioids to the Hurley Drug Company pharmacy,[95] which is the equivalent of 0.80 doses per day per adult and amounts to an estimated 11.6 doses per day per prescription opioid taking adult, more than 5 times higher than the benchmark (Table 14). Cardinal was still distributing nearly half a million dosage units to the pharmacy in 2013,[96] the equivalent of 0.5 doses per day per adult and the equivalent of 7 doses per prescription opioid taking adult per day (Table 14).

[94] *Id.*

[95] *Id.*

[96] *Id.*

Table 14. Cardinal Health Shipments to Hurley Drug Company in Williamson, West Virginia (dosage units)

Year	Oxycodone and Hydrocodone	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2006	807,000	0.80	5.3	11.6
2013	483,840	0.49	3.3	7.0

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Williamson were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

Between 2006 and 2012, Cardinal Health distributed 6,829,680 dosage units of hydrocodone and oxycodone to Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia.[97] This small, West Virginia town had an adult population in the 2010 Census of 1,313 (Table 15). This means that during this seven-year period, Cardinal supplied the equivalent of 2.04 dosage units of opioids per day to every adult in the town, which is equivalent to 29.5 dosage units per prescription opioid taking adult per day. This volume of supply, which is more than 13 times higher than the benchmark, was inconsistent with public health.

[97] *Id.*

Table 15. Cardinal Health Shipments to Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia (dosage units)

Year	Oxycodone and Hydrocodone	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2006-2012	6,829,680	2.04	13.6	29.5

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Mount Gay-Shamrock were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

Although the number of dosage units of hydrocodone and oxycodone sold to Family Discount Pharmacy in 2009 was 1.5 million, the equivalent of a startling 45.4 doses per prescription opioid taking adult per day, Cardinal's shipments continued, as it supplied 1.1 million dosage units in 2012,[98] a level more than 15 times higher than the benchmark and the equivalent of an estimated 33.3 doses per day per prescription opioid taking adult (Table 16).

Table 16. Cardinal Health Shipments to Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia (dosage units)

Year	Oxycodone and Hydrocodone	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2009	1,500,000	3.13	20.9	45.4
2012	1,100,000	2.30	15.3	33.3

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Mount Gay-Shamrock were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

Cardinal Health's supply of 1.1 million dosage units of oxycodone and hydrocodone to Family Discount Pharmacy also exceeds the annual oxycodone

[98] *Id.*

threshold Cardinal set for a much larger pharmacy that it supplied during this same time frame (CVS 219 in Sanford, Florida, a town with more than 54,000 residents), which was [redacted], a level that was set on November 10, 2011.[99] Cardinal Health testified that CVS 219 in Sanford is "much larger than most retail independent pharmacies… ."[100] Distribution of 1.1 million dosage units of oxycodone and hydrocodone to Family Discount Pharmacy, a town of population 1,800 in 2012, a level exceeding a threshold set for a much larger pharmacy and town is inconsistent with public health.

Cardinal Health also set high thresholds for Family Discount Pharmacy and increased those thresholds multiple times in a short period of time without documentation of valid reason for these increases, at volumes that were inconsistent with public health.[101] For example, while the hydrocodone monthly threshold at the start of 2008 was 27,000, by June, 2012, the threshold had increased to 154,500.[102] This would have translated into nearly 1.9 million dosage units of hydrocodone per year, a level that translates into an astronomical 56 hydrocodone pills per prescription opioid taking adult per day. A threshold this

[99] Declaration of Michael A. Moné, Vice President for Supply Chain Integrity, Cardinal Health, in Cardinal Health, Inc. v. Eric Holder, Jr., et al., United States District Court for the District of Columbia, February 3, 2012, p. 25. Pl.4213. CAH_MDL_PRIORPROD_DEA12_00014053.

[100] Id., p. 28.

[101] *Id.*, p. 211-213.

[102] *Id.*, p. 212.

high would allow for significant oversupply to occur. There is also evidence that Cardinal Health increased the hydrocodone threshold for Family Discount Pharmacy on 11 separate occasions within one year, culminating in what amounted to more than a 3-fold increase in less than one year.[103]

The CEO of Cardinal Health admitted under oath that the order volumes it was distributing to both Hurley Drug Company and Family Discount Pharmacy were inappropriate and should have been stopped: "And the answer is yes, I think we would do things very differently today. That kind of order volume would have been picked up and stopped just statistically by our algorithms."[104]

D. McKesson

1. McKesson supplied pharmacies in Cabell County with quantities of opioids that were inconsistent with Public Health.

McKesson shipped large quantities of opioids to Cabell County and City of Huntington that were inconsistent with public health at a time when information that linked excessive supply of opioids to negative public health consequences was available.

McKesson's oversupply is most notable in its distribution of opioids into various Rite Aid stores in Cabell County. Rite Aid also distributed opioids to its

[103] *Id.*, p. 212.

[104] Statement of George Barrett, former CEO, Cardinal Health, before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, May 8, 2018. *Combating the Opioid Epidemic: Examining Concerns about Distribution and Diversion*, p.59. Pl.6480.

own stores, and McKesson did not question Rite Aid about the amount of opioids it was distributing to its own stores.[105] The addition of Rite Aid's own supply to these same stores made McKesson's oversupply more significant.

For example, McKesson shipped an oversupply of opioids to Rite Aid Pharmacy #3311 in Milton, West Virginia, a town with a population of just 2,423 people and 1,926 adults (2010 Census). In particular, in 2008, McKesson supplied Rite Aid Pharmacy #3311 with 56,800 dosage units of oxycodone and 18,240 dosage units of hydrocodone (Table 17), which by itself would have been the equivalent of 1.5 dosage units per prescription opioid taking adult per day. Information regarding Rite Aid's self-distribution would have revealed that Rite Aid was also distributing an additional 167,600 dosage units of hydrocodone to the pharmacy that year, meaning that the total opioid distribution was actually 242,640, which is 0.35 dosage units per adult in the town and the equivalent of 5.0 dosage units per prescription opioid taking adult per day. This large supply of opioids is inconsistent with public health.

[105] Deposition of Michael Oriente. September 6, 2019 at 267-269.

Table 17. McKesson Shipments to Rite Aid Pharmacy #3311 in Milton, West Virginia (dosage units) plus Rite Aid shipments of hydrocodone

Year	Oxycodone	Hydrocodone (McKesson on top; Rite Aid in middle row; total on bottom)	Total	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2006	41,100	8,900 124,700 133,600	174,700	0.24	1.6	3.6
2007	53,000	5,400 159,600 165,000	218,000	0.31	2.1	4.5
2008	56,800	18,240 167,600 185,840	242,640	0.35	2.3	5.0
2009	56,000	20,400 145,500 165,900	221,900	0.32	2.1	4.6
2010	45,100	15,700 144,700 160,400	205,500	0.29	1.9	4.2
2011	46,400	27,160 135,630 162,790	209,190	0.30	2.0	4.3
2012	34,000	30,530 122,530 153,060	187,060	0.27	1.8	3.9
2013	32,200	18,360 131,500 149,860	182,060	0.26	1.7	3.8
2014	40,400	51,260 86,930 138,190	178,590	0.25	1.7	3.7

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Milton were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

During the entire period from 2006 through 2014, McKesson contributed to the supplying of Rite Aid Pharmacy #3311 at a level equivalent to between 3.6 and

5.0 dosage units per prescription opioid taking adult for every day during that ten-year period (Table 17). During this entire period, the oversupply was exacerbated by Rite Aid's own distribution of hydrocodone to this pharmacy.

Precisely the same problem occurred with McKesson's dealings with Rite Aid Pharmacy #968 in Barboursville, a town with an adult population of 3,298 (2010 Census). The combined distribution of hydrocodone from McKesson and Rite Aid itself resulted in an excessive supply of opioids into Barboursville. Information about Rite Aid's own supply of that pharmacy was available and could have been used to reduce McKesson's oversupply.

For example, in 2009, McKesson supplied Rite Aid Pharmacy #968 with 131,100 dosage units of oxycodone and 28,900 dosage units of hydrocodone (Table 18), which by itself would have been the equivalent of a potentially 1.9 dosage units per prescription opioid taking adult per day. Rite Aid was itself distributing an additional 237,200 dosage units of hydrocodone to the pharmacy that year, meaning that the total opioid distribution was actually 397,200, which is 0.33 dosage units per adult in the town and the equivalent of 4.8 dosage units per prescription opioid taking adult per day. The combined volume of opioid supply to this pharmacy was inconsistent with public health.

Table 18. McKesson Shipments to Rite Aid Pharmacy #968 in Barboursville, West Virginia (dosage units) plus Rite Aid shipments of hydrocodone

Year	Oxycodone	Hydrocodone (McKesson on top; Rite Aid in middle row; total on bottom)	Total	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2006	71,300	5,100 224,400 229,500	300,800	0.25	1.7	3.6
2007	78,900	4,200 262,300 266,500	345,400	0.29	1.9	4.2
2008	105,700	6,920 259,300 266,220	371,920	0.31	2.1	4.5
2009	131,100	28,900 237,200 266,100	397,200	0.33	2.2	4.8
2010	129,000	16,600 240,430 257,030	386,030	0.32	2.1	4.6
2011	104,100	39,270 200,070 239,340	343,440	0.29	1.9	4.1
2012	75,700	50,080 175,310 225,390	301,090	0.25	1.7	3.6
2013	60,800	30,920 171,490 202,410	263,210	0.22	1.5	3.2
2014	59,000	66,810 120,990 187,800	246,800	0.21	1.4	3.0

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Barboursville were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

During the entire period from 2006 through 2014, McKesson contributed to supplying Rite Aid Pharmacy #968 with opioids at a level equivalent to between 3.0 and 4.8 dosage units per prescription opioid taking adult for every day during that ten-year period (Table 18). During this entire period, both McKesson and Rite

Aid were supplying the same pharmacy at combined volumes inconsistent with public health.

Overall, the volume of opioids being supplied by McKesson Corporation to Cabell County and the City of Huntington during the period of 2006-2014 was the equivalent of between 5.3 and 7.0 dosage units per prescription opioid taking adult per day, after accounting for the company's share of the oxycodone and hydrocodone market (Table 19).

Table 19. McKesson Corporation Shipments to Cabell County and Huntington, West Virginia

Year	**Dosage units (oxycodone and hydrocodone)**	**Population**	**Adults**	**Doses/ adult/ day***	**Doses per estimated number of prescription opioid taking adults per day****	**Company market share in Cabell County**	**Adjusted doses per prescription opioid taking adult per day***
2006	2,625,460	98,955	79,461	0.09	1.3	0.24	5.4
2007	3,056,120	99,054	79,540	0.11	1.6	0.24	6.7
2008	3,650,050	99,190	79,650	0.13	1.9	0.27	7.0
2009	2,404,160	99,991	80,293	0.08	1.2	0.18	6.7
2010	2,104,500	100,270	80,517	0.07	1.0	0.17	5.9
2011	2,277,220	100,380	80,605	0.08	1.2	0.18	6.7
2012	2,206,290	100,658	80,828	0.07	1.0	0.19	5.3
2013	2,036,800	100,717	80,876	0.07	1.0	0.19	5.3
2014	2,793,110	100,299	80,540	0.10	1.5	0.25	6.0

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Cabell County were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

2. McKesson oversupplied pharmacies in nearby counties in West Virginia with opioid drugs.

In 2006, McKesson supplied Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia with 1,767,400 dosage units of hydrocodone (Table 20).[106] Based on the 2010 Census, the adult population of Mount Gay-Shamrock was 1,313. This means that McKesson supplied the equivalent of 3.69 doses of hydrocodone per day to every adult in the town, a level that is 25 times higher than the benchmark of 0.15. This is enough to supply each prescription opioid taking adult in the town with an astounding 53.5 dosage units per day. This volume of opioid supply was inconsistent with public health.

McKesson distributed another 1,694,800 dosage units of hydrocodone to this same pharmacy in 2007,[107] which is the equivalent of 3.5 doses of hydrocodone per day to every adult in the town (Table 20). This amounts to an estimated 51 doses per day for each prescription opioid taking adult. This distribution of 1,694,800 dosage units amounts to 141,000 dosage units per month. This high-volume supply

[106] House Energy and Commerce Committee. *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*. Washington, DC: U.S. House of Representatives, Energy and Commerce Committee, December 19, 2018.

[107] *Id.*

occurred despite the fact that McKesson had set a threshold of 8,000 dosage units per month[108] to trigger an intense investigation.[109]

Although McKesson stopped supplying the pharmacy for several years in response to an investigation, in 2013, it again supplied the Family Discount Pharmacy with nearly one million dosages of hydrocodone (986,500) (Table 20).[110] This means that McKesson supplied the equivalent of 2.1 doses of hydrocodone per day to every adult in the town during that year, a level that is 14 times higher than the benchmark of 0.15. This is enough to supply eight doses of hydrocodone per day to 25% of the adults in the town for the entire year. It amounts to an estimated 30 doses per day for every prescription opioid taking adult in the town. Even after the oversupply in 2006 and 2007 and the resulting investigation, McKesson continued to provide an oversupply of opioids to the pharmacy in 2013.

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[108] *Id.*

[109] McKesson. Lifestyle Drug Program. July 27, 2007. Hilliard Exhibit 15. Pl.1887. MCKMDL00591949.

[110] House Energy and Commerce Committee, 2018.

Table 20. McKesson Shipments to Family Discount Pharmacy #5 in Mount Gay-Shamrock, West Virginia (dosage units)

Year	Hydrocodone Total	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2006	1,767,400	3.69	24.6	53.5
2007	1,694,800	3.54	23.6	51.3
2013	986,500	2.06	13.7	29.8

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Mount Gay-Shamrock were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

During the period 2006-2007, this small pharmacy—serving a town of 1,800 people—was McKesson's top customer in West Virginia.[111] McKesson's significant oversupply was inconsistent with public health.

According to McKesson's own data, the national average amount of dispensed hydrocodone to a retail pharmacy is approximately 131,000 dosage units per year, and according to its own regional data, the average supply per pharmacy in the Appalachian region was 24,000 dosage units per year.[112] Thus, even according to McKesson's own data, the distribution of nearly one million doses to the Family Discount Pharmacy in 2013 was grossly unusual. McKesson had set a monthly hydrocodone threshold for Family Discount Pharmacy at the

[111] *Id.*

[112] McKesson. Understand ARCOS Data. P1.1354. MCKMDL00407449.

unconscionable level of 112,000 dosage units *per month*,[113] even though the average hydrocodone distribution to retail pharmacies was 131,000 dosage units *per year* and that this was a town with an adult population of 1,300 that had another retail pharmacy in the town and several national account pharmacies within ten miles.[114]

Even after this gross oversupply to Family Discount Pharmacy in 2013, an internal memo reveals that on March 14, 2014, the Director of Regulatory Affairs for McKesson's North Central region recommended "that McKesson continue the shipment of controlled substances to this account, adjust thresholds accordingly and continue to monitor order patterns."[115] McKesson's continued oversupply was inconsistent with public health.

In 2012, McKesson approved an application for service from Family Discount Pharmacy in Stollings, West Virginia (same owner as the Mt. Gay-Shamrock pharmacy of the same name) even though it reported average monthly sales of hydrocodone of 40,000 dosage units for a town of 316 people.[116] This is

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[113] McKesson. Hydrocodone thresholds. Family Discount Pharmacy. March 2010-April 2014. Pl.829. MCKMDL00332365.

[114] McKesson Regulatory Investigative Report from Dave Gustin, Director of Regulatory Affairs, McKesson Pharma, NC region, March 24, 2014 MCKMDL0032657.

[115] McKesson Regulatory Investigative Report from Dave Gustin, Director of Regulatory Affairs, McKesson Pharma, NC region, March 24, 2014. MCKMDL0032657.

the equivalent of 4.2 doses per person per day and would amount to an estimated 61 doses per prescription opioid taking adult per day, far greater than an amount that would be consistent with public health.

As part of the application, the pharmacy supplied its dispensing records for the past six months. During this period, Dr. Robert McCleary had filled 125 prescriptions for hydrocodone with 74 refills.[117] In a town with approximately 230 adults, this is enough prescriptions for 54% of the adults in the town to be taking hydrocodone. Publicly available records reveal that on February 3, 2007, the West Virginia Board of Osteopathy reached with Dr. McCleary "a consent agreement including requiring attending AA/NA meeting, random drug screens and monitoring" and that on September 13, 2007, his medical license was suspended.[118] He was required to undergo counseling or therapy and eventually his license was reinstated but was put on five-year probation, meaning that he was still on probation or just off probation at the time of Family Discount Pharmacy #2's application.

[116] McKesson. Pharmacy Questionnaire. Family Discount Pharmacy of Stollings, September 26, 2012. Pl.859. MCKMDL00331379.
[117] *Id.*, p.75 (Pl.859.75)

[118] West Virginia Board of Osteopathy. *2008 Annual Report*. December 3, 2008. http://www.wvlegislature.gov/legisdocs/reports/agency/B11_FY_2008_275.pdf (last retrieved April 27, 2020).

Furthermore, an examination of the Family Discount Pharmacy #2 sales records reveals that during this six-month period, Dr. James E. Prommersberger—a podiatrist (a medical subspecialty that focuses on foot and ankle problems)—provided 141 hydrocodone prescriptions with 67 refills.[119] In a town with approximately 230 adults, this is enough prescriptions for 61% of the adults in the town to be taking hydrocodone prescribed by a foot doctor, which is extremely concerning from a public health perspective. Indeed, just a few years later, the West Virginia Board of Medicine issued a consent order to Dr. Prommersberger, suspending his medical license for three years after an investigation revealed that "between December 20, 2014 and December, 2015, over 1,100 prescriptions for controlled substances were dispensed in the state of Kentucky pursuant to prescriptions written by Dr. Prommersberger, ninety percent of which were written for a hydrocodone combination product, with the majority written for quantities of 60 or greater per month."[120] As part of the consent order, Dr. Prommersberger was not permitted to prescribe more than a 14-day supply of opioid medication.

McKesson's supply also provided opioids to fill the prescriptions of Dr. Scott Siegel. He asked a small pharmacy in a town of just 230 adults to fill 196

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[119] McKesson. Pharmacy Questionnaire. Family Discount Pharmacy of Stollings, September 26, 2012. MCKMDL00331365, p.83.

[120] West Virginia Board of Medicine. Consent Order. In Re: James Edwin Prommersberger, D.P.M. June 29, 2017.

prescriptions for hydrocodone in a six-month period, single-handedly accounting for the disbursement of 11,819 dosage units of hydrocodone,[121] enough to supply every adult opiate patient in the entire town with four dosage units per day all by himself. The prescribing patterns of these doctors whose prescriptions were filled by McKesson's customer pharmacy indicate opioid use inconsistent with public health.

During the years 2006 and 2007, McKesson supplied Sav-Rite No. 1 pharmacy in Kermit, West Virginia with approximately 4.96 million dosage units of hydrocodone and oxycodone (Table 21).[122] The adult population of Kermit in the 2010 Census was 300. This means that McKesson supplied the equivalent of 22.6 doses of hydrocodone/oxycodone per day to every adult in the town during those two years, a level that is 151 times higher than the benchmark of 0.15. Using the CDC estimate that 6.9% of adults are taking prescription opioid medication, this amounts to an astounding 328 doses per day for each prescription opioid taking adult. This pharmacy was the third highest purchaser of hydrocodone and oxycodone from McKesson in West Virginia during those two years.[123] McKesson did not terminate sales to this pharmacy until mid-November 2007. This

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[121] McKesson. Pharmacy Questionnaire. Family Discount Pharmacy of Stollings, September 26, 2012. MCKMDL00331365, p.91.
[122] House Energy and Commerce Committee, 2018.

[123] *Id.*

distribution occurred despite the fact that McKesson had set a threshold of 8,000 dosage units per month to trigger an intense investigation.[124] McKesson's distribution to Sav-Rite No. 1 far exceeded its own threshold for investigating a potential public health concern.

Table 21. McKesson Shipments to Sav-Rite No. 1 pharmacy in Kermit, West Virginia (dosage units)

Year	Hydrocodone and Oxycodone Total	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2006/2007	4,955,710	22.6	151	328

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Milton were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

The CEO of McKesson acknowledged under oath before Congress that these shipments to Sav-Rite No. 1 pharmacy in Kermit, West Virginia represented an oversupply of opioids and that "in hindsight, we wish we would have terminated that relationship sooner."[125] The McKesson Corporation CEO further stated under oath: "I believe our relationship with Sav-Rite should have been terminated immediately."[126] The CEO also admitted that its monitoring systems were

[124] *Id.*
[125] Statement of John Hammergren, President and CEO, McKesson Corporation, before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, May 8, 2018. *Combating the Opioid Epidemic: Examining Concerns about Distribution and Diversion*, p.48. Pl.6480.

[126] *Id.*, p. 53.

inadequate at the time which led to the acknowledged failure: "Our systems at the time were not automated enough, certainly, and we didn't flag it fast enough and get it fast enough. … We did not manage that Sav-Rite relationship and certainly didn't do it soon enough."[127]

During the period June through August, 2014, McKesson supplied Hurley Drug Company in Williamson, West Virginia—a town with an adult population of 2,731 (2010 Census)—with a monthly average of 37,800 dosage units (Table 22).[128] This translates into an average of 0.46 dosage units per adult per day, which is the equivalent of 6.6 dosage units per prescription opioid taking adult per day.

Table 22. McKesson Shipments to Hurley Drug Company in Williamson, West Virginia (dosage units)

Year	Hydrocodone and Oxycodone Average per month	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
June-August 2014	37,800	0.46	3.1	6.6

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Williamson were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

In 2007, McKesson supplied the Westside Pharmacy in Oceana, West Virginia with an oversupply of opioid drugs. Despite the fact that Oceana had a population of only 1,100 adults, McKesson supplied this pharmacy with 156,900

[127] *Id.*, pp. 55-56.

[128] McKesson. Chart of distributions to Hurley Drug Company, 06/01/14-08/31/14. Pl.887. MCKMDL00331678.

dosage units of oxycodone and 265,000 dosage units of hydrocodone, for a total of 421,900 dosage units (Table 23).[129] This equates to 1.05 dosage units per adult per day, a level that is 7 times higher than the benchmark of 0.15. Based on an average 6.9% of the adult population taking prescription opioids during this time, this quantity was enough to supply every prescription opioid taking adult with 15 dosage units every day throughout the entire year.

Table 23. McKesson Shipments to Westside Pharmacy in Oceana, West Virginia (dosage units)

Year	Hydrocodone and Oxycodone Total	Dosage units per adult per day*	Times higher than benchmark	Dosage units per estimated number of prescription opioid taking adults per day**
2007	421,900	1.05	7.0	15.2

*Dosage units per all adults in the population.
**Assumes 6.9% of adults in Oceana were taking prescription opioid medication, which is the average number of adults who took a prescription opioid in the last 30 days, as documented by CDC data. Opioid distribution data from ARCOS and Defendant Transactional data.

My opinions expressed above regarding the distribution of an oversupply of opioids into Cabell and nearby counties by AmerisourceBergen, Cardinal Health, and McKesson Corporation that was inconsistent with public health are in accord with the findings and conclusions of a 2018 Congressional investigation.[130] The report of the investigative committee agreed with my opinions that: (1) the distributor Defendants oversupplied pharmacies in Cabell and nearby West Virginia counties with opioids in a manner inconsistent with public health and (2)

[129] Pl.6384. Opioid Shipments to Pharmacies in Wyoming County, WV 2006-2014

[130] House Energy and Commerce Committee. *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*. Washington, DC: 2018. Pl.2060.

the distributor Defendants continued to oversupply these pharmacies for months or even years despite available evidence that such distribution was inconsistent with public health. The relevant report findings and conclusions are as follows:

> The effects of the opioid epidemic have been most acutely felt in West Virginia, which had the highest overdose death rate in the country in 2016. Reporting by the Charleston Gazette-Mail found that wholesale drug distributors dispersed more than 780 million doses of hydrocodone and oxycodone to West Virginia between 2007 and 2012, with individual distributors, in some cases, sending volumes of controlled substances to small-town pharmacies that far exceeded what could be considered reasonable to meet the legitimate medical needs of area residents. In one instance, distributors sent more than 20.82 million doses of hydrocodone and oxycodone to two pharmacies located four blocks apart in a town of approximately 3,000 people. In another instance, a single pharmacy in a town of 406 people received nearly 13 million doses of hydrocodone and oxycodone from all distributors between 2006 and 2012. The extraordinary volume and pattern of opioid shipments, such as those sent to pharmacies in small West Virginia towns, were in the DEA's words "red flags of diversion."
>
> In the areas of West Virginia for which the Committee obtained ARCOS data, there were more than 131 pharmacies that received between two million and five million doses of hydrocodone between 2006 and 2016. Seventeen pharmacies received more than five million doses of hydrocodone and oxycodone. Five of those pharmacies received more than 10 million doses. Four of the five pharmacies that received more than 10 million doses of hydrocodone and oxycodone were located in the same zip-code prefix area: Family Discount Pharmacy, Hurley Drug Company, Sav-Rite Pharmacy No. 1, and Tug Valley Pharmacy. These four pharmacies, as well as three others extensively discussed in this report, are all located within a short distance of each other in southern West Virginia. For example, the distance between the Sav-Rite No. 1 Pharmacy in Kermit, West Virginia, and Westside Pharmacy in Oceana, West Virginia is less than 65 miles.

> [T]he extraordinary volume of shipments in West Virginia was a harbinger of possible breakdowns in distributors' oversight of their customers, including their suspicious order monitoring systems. … the Committee's investigation revealed several instances where distributors supplied West Virginia pharmacies with a volume of opioids that should have raised red flags, particularly when viewed in the context of what would be considered reasonable to support the legitimate medical needs of the local population. Distributors also at times shipped millions of opioid pills to small-town pharmacies with very little corresponding due diligence. In other instances, distributors had in their possession due diligence materials that should have prompted them to conduct independent investigations of certain pharmacy customers or required them to more frequently report suspicious orders to DEA. The Committee's investigation found, however, that distributors continued to ship opioids to these pharmacies for months and, in some cases, even years.

The report also concluded that the Chief Executive Officers of all three companies (AmerisourceBergen, Cardinal Health, and McKesson Corporation) admitted that the volume of opioids shipped to the above West Virginia pharmacies represented a gross oversupply, should have been red flags, and that if the same situation occurred today, they would have immediately cut off these pharmacies. The CEOs also acknowledged that their vetting of the pharmacies in question was inadequate:

> Asked at the hearing whether their companies previously failed to maintain effective controls to prevent opioid diversion, distributor witnesses acknowledged that in hindsight they could have done more. Mr. Barrett of Cardinal Health apologized to West Virginians for Cardinal's actions, testifying that if the company were presented with the same red flags today, it would have more carefully vetted some of the pharmacies in question: To the people of West Virginia, I want to express my personal regret for judgments that we'd make differently today with regard to two pharmacies that have been a particular focus

> of this subcommittee. With the benefit of hindsight, I wish we had moved faster and asked a different set of questions. I'm deeply sorry that we did not. Mr. Hammergren of McKesson expressed similar sentiments, noting that "there clearly were certain pharmacies in West Virginia that were bad actors." While Mr. Hammergren noted that McKesson terminated business relations with some West Virginia pharmacies, he said "[i]n hindsight, I would have liked to have seen us move much more quickly to identify the issues with these pharmacies." Mr. Collis of AmerisourceBergen … conceded the massive volume of opioids that flooded small towns in West Virginia could have been a symptom of an industry-wide problem. During a transcribed interview with Committee staff, Dr. Mastandrea of Miami-Luken expressed regret over a news article regarding a federal investigation into the Sav-Rite pharmacies in Kermit, West Virginia, both of which were Miami-Luken customers, stating: "If I'm not mistaken, this particular individual pleaded guilty to drug diversion and served time –that owned Sav-Rite Pharmacy. How in God's name we participated in supplying this individual product when, in hindsight, clearly this was drug diversion. A picture of this pharmacy would be next to the definition in the dictionary. No one was paying attention. It's an abomination.

The examples provided herein to demonstrate that Defendants were oversupplying pharmacies in Cabell County and in nearby counties in West Virginia are just that – examples. They are not intended as an exhaustive list of each and every instance that I view to be an oversupply. Looking, through a public health lens, at the overall supply of opioids into Cabell County by AmerisourceBergen, Cardinal Health, and McKesson, it is my opinion that all three of these distributors were shipping excessive amounts of opioids into Cabell County as a whole throughout the entire period covered by this report and this excessive supply contributed to the public health crisis that occurred in Cabell County and the City of Huntington during this time period.

VII. Information was Available regarding the Growing Opioid Public Health Crisis and the Extent to Which Oversupply Contributed to and Caused that Crisis

A. All Companies

In 2002, the General Accounting Office (GAO) published a report entitled "Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion."[131] The report described the growing opioid abuse problem in the nation:

> The increasing diversion of prescription drugs for illegal use is a disturbing trend in the nation's battle against drug abuse. Prescription drug diversion is the channeling of licit pharmaceuticals for illegal purposes or abuse. It can involve activities such as "doctor shopping" by individuals who visit numerous physicians to obtain multiple prescriptions, illegal sales of prescription drugs by physicians or pharmacists, and prescription forgery. The most frequently diverted prescription drugs are those that are prone to abuse, addiction, and dependence, such as hydrocodone (the active ingredient in Lortab and many other drugs), diazepam (Valium), methylphenidate (Ritalin), and oxycodone (the active ingredient in OxyContin and many other drugs).

In 2003, the General Accounting Office (GAO) published a report entitled "OxyContin Abuse and Diversion and Efforts to Address the Problem."[132] The report noted that: "During a December 2001 congressional hearing, witnesses from

[131] General Accounting Office. *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*. Washington, DC: GAO, May 2002. Pl.1076.

[132] United States General Accounting Office. *OxyContin Abuse and Diversion and Efforts to Address the Problem*. Washington, DC: GAO, December 2003. Pl.1087.

DEA and other law enforcement officials from Kentucky, Virginia, and West Virginia described the growing problem of abuse and diversion of OxyContin."

In 2006, all distributors received a memorandum from the DEA which stated its purpose was to "reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."[133] The letter emphasized that "Distributors are, of course, one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a *substantial and detrimental effect on the health and general welfare of the American people.*" (emphasis is mine).

In 2007, all distributors received a letter from the DEA reminding them that they have a responsibility to maintain effective controls against diversion.[134]

By 2011, public health sources commonly reported a substantial increase in the opioid overdose death rate from 1999-2008. West Virginia was also reported as having the second highest overall drug overdose death rate of any state in the

[133] Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA, September 27, 2006. Pl.1464. (Exhibit 4 – Hilliard deposition).

[134] Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA to all registrants, December 27, 2007. Exhibit 23 in Hartle deposition. MCKMDL00478910.

nation in 2008 (25.8 per 100,000), a rate that was five times higher than that of the state with the lowest rate (Nebraska at 4.5 per 100,000) and more than twice as high as the national rate (11.9 per 100,000).[135]

B. AmerisourceBergen

In 2008, AmerisourceBergen was in possession of a presentation at a joint meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA.[136] The very first slide noted that there was a drastic increase in prescription opioid drug overdose deaths in the U.S. between 1999 and 2004. The second slide showed that the rise in opioid overdose deaths paralleled a similar dramatic increase in total sales of prescription opioids.

Also in 2008, AmerisourceBergen's documents reflect that Cardinal Health was being investigated by DEA for inappropriate distribution of hydrocodone and that the investigation resulted in the suspension of three Cardinal Health distribution centers' authorization to dispense controlled substances, as well as in a drop in the company's stock value.[137] AmerisourceBergen scheduled a high-level meeting to discuss controlling diversion of opioid prescription drugs.

[135] Paulozzi LJ, Jones CM, Mack KA, Rudd RA. Vital signs: Overdoses of prescription opioid pain relievers—United States, 1999-2008. *MMWR* 2011; 60(43):1487-1492.

[136] Van Zee A. FDA: Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee & the Drug Safety & Risk Management Advisory Committee, May 6, 2008. Pl.766.

In 2009, AmerisourceBergen was in possession of a newspaper article titled "Prescription drug overdoses termed 'epidemic' in West Virginia."[138] According to the article: "West Virginia tops the nation in per capita prescription drug overdoses, and police believe even more people will become addicted and die – if the problem does not stop."

In 2010, AmerisourceBergen was in possession of a presentation by the regulatory section of DEA regarding the responsibilities of distributors.[139] The presentation discussed the importance of knowing your customers in order to be able to identify suspicious orders and emphasized that such orders should not be shipped unless and until they are investigated and found to be legitimate.

In 2011, officials in AmerisourceBergen's controlled substances monitoring program and government affairs offices circulated by email of a song parody from a Florida newspaper regarding the opioid public health crisis in West Virginia that was "to be sung with tune from Jimmy Buffett's Margaritaville."[140] The song has lines such as: "Headin' for strip malls, drivin' till night falls, all of these tourists,

[137] Email from Burt Rosen to Rita Norton (AmerisourceBergen), January 31, 2008. Pl.6542. PPLP004301234.

[138] Email from Bruce Gundy entitled "Rx drug overdoses termed 'epidemic' in W Va," January 19, 2009. Pl.6470. ABDC-STC002214953

[139] Regulatory Section. DEA Headquarters. ODG (presentation), 2010. Pl.358.

[140] Email from Julie Eddy to Chris Zimmerman and Steve Mays. AmerisourceBergen, February 25, 2011. Pl.6507. ABDCMDL08090633.

carrying cash looking' for pill mills…Wastin' away in OxyContinville, Searchin' for my last doctor to shop."

Also in 2011, officials in AmerisourceBergen's corporate security and regulatory affairs offices circulated a another parody song about the opioid epidemic in West Virginia, including the existence of pill mills, and featuring a West Virginia "hillbilly" driving down to Florida to fill his car with opioids.[141] The first verse (sung to the melody of the Beverly Hillbillies) was: "Come and listen to a story about a man named Jed, a poor mountaineer, barely kept his habit fed, Then one day he was lookin at some tube, And saw that Florida had a lax attitude. About pills that is, Hillbilly Heroin, "OC".

As late as 2015, a consultant report on AmerisourceBergen's Corporate Security and Regulatory Affairs department's procedures for preventing drug diversion concluded that these procedures were inadequate; among other things, the report noted that "ABC does not have a policy to determine which associate(s) at the distribution center are responsible for reviewing orders. Although all associates who have access to the OMP system are required to be trained in reviewing orders, there is no consistency with respect to who is reviewing these

[141] Email from Julie Eddy to Chris Zimmerman. AmerisourceBergen, April 22, 2011. Pl.6456. ABDCMDL00569571.

orders. This presents a significant risk area because the company needs to be compliant with DEA regulations and able to explain and defend their decisions."[142]

In 2007, the DEA issued an immediate suspension order to the AmerisourceBergen distribution center in Orlando, Florida, alleging that the company failed to effectively control against diversion of controlled substances.[143] According to the company: "The license was suspended in April 2007, because DEA alleged that the distribution center had not maintained effective controls against diversion of controlled substances by retail internet pharmacies."[144] Specifically, the DEA alleged that "this office was selling large quantities of controlled substances to rogue Internet pharmacies. The investigation has revealed that several of their largest purchasers of hydrocodone were pharmacies engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. In spite of being warned by DEA about the characteristics of rogue internet pharmacies, this office distributed 3.8 million

[142] FTI Consulting, Inc. Health Solutions Practice. *AmerisourceBergen Corporation CSRA Process Review, Phase I: Narrative Report.* Pl. 6261. ABDCMDL00274105, p. 10-11. Report is undated, but Pl.6263 ABDCMDL00250023 makes it clear that report was received and reviewed in September 2015.

[143] I am not using this evidence to conclude that AmerisourceBergen violated the Controlled Substances Act or that it admitted to these violations. I am using this evidence solely to establish that there were repeated allegations against the company.

[144] AmerisourceBergen. DEA resinstates AmeriSourceBergen's Orlando Distribution Center's suspended license to distribute controlled substances (press release). August 27, 2007. https://www.sec.gov/Archives/edgar/data/1140859/000119312507189992/dex991.htm.

dosage units of hydrocodone products between January 1, 2006 and January 31, 2007 to rogue pharmacies."[145]

The DEA alleged that in 2006, AmerisourceBergen distributed more than 1 million dosage units of hydrocodone to a single pharmacy (Grand Pharmacy) in New Port Richey, Florida, a town of only 17,018 in 2006, "under circumstances that clearly indicated that Grand Pharmacy was engaged in the diversion of controlled substances."[146] Moreover, AmerisourceBergen "also supplied generic and brand name hydrocodone and hydrocodone combination products under similarly suspicious circumstances to Discount Mail Meds, LLC, Medassist RX, LLC, and Avee Pharmacy, Inc, among others. Respondent distributed hydrocodone under the following circumstances that should have alerted Respondent that the pharmacies were diverting hydrocodone: a. Respondent distributed hydrocodone to each of the named pharmacies, and others, in amounts that far exceeded what an average pharmacy orders to meet the legitimate needs of its customers. Respondent knew that orders of an unusual size were "suspicious" as that term is med in 21 C.F.R. § l 301.74(b)."[147]

[145] DEA. DEA suspends Orlando branch of drug company from distributing controlled substances (press release), April 24, 2007. https://www.dea.gov/sites/default/files/divisions/mia/2007/mia042407p.html.

[146] DEA. Order to Show Cause and Immediate Suspension of Registration, April 19, 2007. Pl.6132. ABDCMDL00269383, p. 2.

[147] *Id.*, p. 2.

Furthermore, the DEA alleged "Public information regarding several of Respondent's pharmacy customers was readily available to Respondent. Had Respondent attempted to learn about these pharmacies prior to filling the suspicious orders placed by the pharmacies, Respondent would have known that many of the named pharmacies were filling prescriptions that were issued by physicians acting outside the usual course of professional practice in violation of 21 CF.R. § 1306.04. Specifically, the prescriptions filled by the pharmacies were issued by physicians who did not conduct a medical examination of the customers, but rather wrote prescriptions for controlled substances that were ordered by customers over the Internet."[148]

C. Cardinal Health

In 2005, the DEA informed Cardinal that there was a problem with drug diversion, especially of hydrocodone, by internet pharmacies.[149] An email from the vice president of quality and regulatory affairs noted that any pharmacy purchasing more than 5,000 dosage units of hydrocodone per month raised a red flag, and he asked to be contacted. A regional manager of quality and regulatory affairs responded in a way suggesting that the company did not at the time have an

[148] *Id.*, p. 2.

[149] Email from Steve Reardon to Don Bennett, August 30, 2005. Cardinal Health. Pl. 4598. CAH_MDL_PRIORPROD_DEA07_02088028.

appropriate monitoring program, stating: "Once we develop a due diligence and monitoring program, it would become part of the audit checklist."

In 2008, a Cardinal Health consultant audit stated that Cardinal's suspicious order monitoring system was insufficient "to meet the regulatory requirements without additional real-time monitoring capabilities (though we understand Phase II is under development and will address a number of these issues)."[150] In another email that same year, Cardinal Health was told again by the consultant auditor that "Cardinal does not yet have a system for detecting all suspicious orders."[151]

A 2008 Cardinal Health presentation on supply chain integrity noted that: "the 'cost' of noncompliance reaches more than just financial statements," depicting potential coverage of any breaches by major news organizations and the possible resulting headlines.[152] The presentation emphasized the importance of "historical analysis" and "threshold setting."

The DEA repeatedly accused Cardinal of inadequately controlling the diversion of opioid drugs.

[150] Letter from Cegedim Dendrite Compliance Solutions to Jodi Avergun, January 23, 2008. CAH_MDL2804_03309960.

[151] Email from Jodi Avergun to Michael Mone, January 7, 2008. CAH_MDL_PRIORPROD_DEA07_00110665.

[152] Hartman M, Senior Vice President of Supply Chain Integrity and Regulatory Operations at Cardinal Health. Supply Chain Integrity (presentation), November 6, 2008. CAH_MDL2804_00225017.

Cardinal Health has repeatedly been cited by the DEA for failure to maintain effective controls against the diversion of opioids. Even after receiving immediate suspension orders for three of its distribution centers in 2007 and 2008 (and an order to show cause for a fourth) and after entering into a settlement with the DEA regarding these alleged violations, Cardinal Health was again served an immediate suspension order in 2012 for one of its facilities and then in 2016, agreed to pay a $44 million fine to resolve this action.[153]

The facts regarding this series of allegations were summarized by the D.C. District Court[154]:

> This is not the first time the DEA has taken enforcement action against Cardinal, or even against its Lakeland Facility. Between November 28, 2007, and December 7, 2007, DEA Administrator Michele Leonhart issued immediate suspension orders to three Cardinal facilities, one of which was the Lakeland Facility. Administrator Leonhart "concluded that the three facilities posed an imminent danger to public health or safety based on a DEA investigation revealing that Cardinal Lakeland failed to maintain effective controls against diversion." And on January 30, 2008, the DEA issued an order to show cause (but not an ISO) to revoke the registration of another Cardinal facility located in Stafford, Texas, again "based on the failure to maintain effective controls against diversion." As a result of these allegations, Cardinal agreed to pay a civil fine of $34 million. Cardinal also entered into a Memorandum of Agreement with the DEA in which it agreed to "maintain a compliance program designed to detect and prevent [the] diversion of controlled substances as required under the CSA and applicable DEA

[153] I am not using this evidence to conclude that Cardinal Health violated the Controlled Substances Act or that it admitted to these violations. I am using this evidence solely to establish that there were repeated allegations against the company.

[154] Parentheticals and citations have been omitted for ease of reading.

regulations." As the backdrop of the action taken by the DEA that precipitated this case, the government asserts that the volume of oxycodone (a Schedule II drug) distributed to Cardinal Lakeland's top four retail customers—CVS Store 219, CVS Store 5195, Gulf Coast, and CareMed ("the four pharmacies")—has increased exponentially since the parties entered into the MOA in 2008. As a result, the government contends that the DEA repeatedly notified Cardinal of its need to exercise greater diligence at the Lakeland Facility to detect suspicious activity by its customers. Cardinal then terminated distribution of controlled substances to Caremed on September 26, 2011, and Gulf Coast on October 5, 2011, but continued to distribute to the two CVS pharmacies. On October 18, 2011, the DEA executed Administrative Inspection Warrants at the four pharmacies, after which both Gulf Coast and Caremed voluntarily surrendered for cause their DEA registrations. A few days later, on October 26, 2011, the DEA executed a warrant at Cardinal's Lakeland Facility to determine whether Cardinal "failed to report suspicious orders to the DEA." On November 8, 2011, the DEA issued an administrative subpoena to Cardinal for information regarding its sales of oxycodone and other drugs as well as its compliance mechanisms. Cardinal thereafter lowered its oxycodone distribution thresholds for CVS Store 219 on November 10, 2011, and CVS Store 5195 on December 16, 2011. The government contends that "[t]he DEA's investigation of Cardinal and its top four retail customers revealed a staggeringly high and exponentially increasing rate of oxycodone distribution from the Lakeland facility." Based on these high volumes and information gleaned from its investigation of Cardinal and the four pharmacies, the DEA determined that "Cardinal failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels, including Cardinal's failure to conduct due diligence of its retail pharmacy chain customers." Finding that this conduct violated Cardinal's obligations under the CSA and the 2008 MOA, and that Cardinal Lakeland's continued registration posed an "imminent danger to the public health and safety," the DEA issued an order to show cause and immediate suspension order to the Lakeland Facility on February 2, 2012.[155]

[155] Cardinal Health, Inc. v. Holder, Civil Action No. 2012-0185 (D.D.C. 2012), District Court, District of Columbia (Filed: March 7th, 2012).

The suspension order was based on the following conclusions based on a DEA investigation: "DEA concluded that over a period of approximately 3 years, November 2008 to December 2011, Cardinal's anti-diversion controls were inadequate to meet their due diligence responsibilities. This conclusion was based on the totality of several factors. Some of the most important factors were: (i) exceedingly large increasing volume of shipments of oxycodone to its largest Florida retail customers, which volumes were supported by inadequate documentation; (ii) a low number of suspicious orders reported; (iii) a low number of on-site visits to these top retailers and no site visits to retail chain pharmacy customers; and (iv) evidence that Cardinal's due diligence practices were inconsistent with both the 2008 MOA and Cardinal's own policies the purpose of which was to reduce diversion."[156]

The alleged volume of opioids supplied to individual pharmacies was staggering:

> Between November 1, 2008 and December 31, 2011, Cardinal Lakeland sold over 12.9 million dosage units of oxycodone to its top four customers. From 2008 to 2009, Cardinal's oxycodone sales to its top four retail pharmacy customers increased approximately 800%. … Cardinal's other Florida retail pharmacies received, on average, 5,364 dosage units per month from October 1, 2008 through December 31, 2011 based on 66,286 pharmacies, which equates to 64,368 dosage units, annually.[157]

[156] Declaration of Joseph Rannazzisi, Deputy Assistant Administrator for DEA's Office of Diversion Control. In Cardinal Health Inc. v. Eric Holder, Jr., Attorney General, et al. Civil Action No. 1:12-cv-185 (RBW). United States District Court for the District of Columbia. Filed February 10, 2012. Pl. 585.1.

In other words, the allegation is that Cardinal Lakeland sold, on average, more than 1 million dosage units of oxycodone per year to its top four customers, but an average of only 64,368 to its other customers. This is more than a 15-fold difference. According to the results of DEA's investigation, in 2011 alone, Cardinal supplied 3,012,500 dosage units of oxycodone to two CVS stores in Sanford, Florida, a 47-fold difference from the average.[158]

The alleged volume of hydrocodone sold to a smaller pharmacy—Horen's Drugstore—is similarly staggering:

> Despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies such as Horen's Drugstore, and despite the public information readily available to Respondent regarding Horen's Drugstore's association with rogue Internet pharmacy websites, Respondent repeatedly supplied Horen's Drugstore with excessive amounts of hydrocodone. Specifically, Respondent distributed in excess of 600,000 dosage units of hydrocodone from March 2007 through September 2007; including over 116,000 dosage units in July; over 129,000 dosage units in August; and over 122,000 dosage units in September.[159]

The DEA also alleged that Cardinal Health ignored or violated its own standards in shipping these high volumes of opioids.[160] One of the allegations was

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[157] *Id.*

[158] *Id.*

[159] *Settlement and Release Agreement and Administrative Memorandum of Agreement between DEA and Cardinal Health, Inc.*, October 2, 2008. Pl. 4230. CAH_MDL_PRIORPROD_DEA12_00001571.

[160] Declaration of Joseph Rannazzisi, Deputy Assistant Administrator for DEA's Office of Diversion Control, 2012, p. 28-33.

that Cardinal regularly exceeded its own distribution thresholds: "Cardinal set monthly thresholds for oxycodone distributions to each of its stores. But from April 2009 to August 2011, Cardinal disregarded the oxycodone thresholds for its top four retailers at least 44 times, sometimes by a few thousand pills and sometimes by tens of thousands. This unexplained disregard for its own thresholds suggests that Cardinal did not take its own policies seriously."[161] A DEA exhibit documented the numerous violations of oxycodone thresholds by pharmacies supplied by the Lakeland facility.[162]

According to the allegations that triggered the immediate suspension orders back in 2007 and 2008, the amount of opioids that Cardinal Health was accused of supplying to pharmacies exhibiting signs of diversion was enormous.[163] According to DEA testimony:

> DEA immediately suspended Cardinal Lakeland based on its conclusion that, for approximately 2 years and two months, between August 2005 and October 2007, the facility 'distributed over 8,000,000 dosage units of hydrocodone combination products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels.' The ISO noted that, although the average retail pharmacy in Florida distributes 'less than 8,400 dosage units of hydrocodone per month,' the ten retail pharmacies that Cardinal Lakeland supplied distributed considerably more. Monthly averages at those ten pharmacies ranged from 11,075

[161] *Id.*, p.29.

[162] DEA. Cardinal Health – Lakeland: Thresholds Exceeded. DEA, 2011. Government Exhibit 21. Docket No. 12-32. CAH_MDL_PRIORPROD_DEA12_00004353.

[163] *Id.*, p.18.

> dosage units to a high of 287,025 dosage units. The ISO alleged that the 'unusual size' of some of the orders, among other factors, should have prompted Cardinal to conclude that the orders 'were suspicious as that term is used in' the regulations.[164]

In 2016, Cardinal Health reached a $34 million settlement with the U.S. Attorney's Office in Florida and the DEA, in which "Cardinal Health acknowledged that, from January 1, 2009 to May 14, 2012, it failed to comply with regulations requiring reports of pharmacies' suspicious orders of certain narcotic medications."[165]

Also in 2016, Kinray, LLC, a subsidiary of Cardinal Health, reached a $10 million settlement with the U.S. Attorney for the Southern District of New York and the DEA, in which it acknowledged that: "Between January 1, 2011 and May 14, 2012, Defendant failed to inform DEA that certain orders for controlled substances it received from some customers were suspicious, as required by 21 C.F.R. § 1301.74(b)."[166]

Finally, as early as November 2006, Cardinal Health's internal documents discuss a problem with its threshold system for oxycodone distribution. Speaking

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[164] *Id.*, p.18.

[165] Department of Justice. United States reaches $34 million settlement with Cardinal Health for civil penalties under the Controlled Substances Act (press release), December 23, 2016. Orlando, FL: U.S. Attorney's Office, Middle District of Florida. https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under.

[166] *Consent Order*. United States of America v. Kinray, LLC. United States District Court, Southern District of New York. 16 Civ. 9767-RA, December 22, 2016. Pl.4222.

about the fact that some customers are "getting 5 or 6 times more" than the thresholds, one of the compliance staff members wrote in an email: "We're going to run into a potential DEA problem if we don't get this straightened out." The reply back from another staff member was: "That is what I am afraid of. Ken hinted during our last phone call that our system should have kept this from happening. I tip-toed around that but it is obvious that something is broken when the limiters that were keyed at corporate are not keeping my customers from ordering this much, and we have other items that do not have limiters at all."[167]

D. McKesson Corporation

As early as 2000, McKesson had a drug operations manual section on controlled substances that made clear the company's responsibility to "prevent diversion of abusable substances into illicit traffic while ensuring their availability for legitimate medical purposes."[168] The manual emphasized that: "It is extremely important that McKesson employees comply fully with the regulations and the following guidelines." The manual covers monthly reporting of data to ARCOS as well as suspicious order detection and reporting.

[167] Cardinal Health. E-mails between Rafael Varela and Elaine Troutman, November 7, 2006. Pl.4324. CAH_MDL_PRIORPROD_DEA07_00849441.

[168] McKesson. Drug Operations Manual. Section 55 – Controlled Substances. July, 2000. Exhibit 12 in Hartle deposition. MCKMDL00337660.

At a 2005 meeting between McKesson and DEA, the DEA discussed a problem with internet pharmacies in Florida.[169] There was internal concern within DEA about whether McKesson was taking the problem seriously.

At a 2006 meeting with the DEA, McKesson officials were warned that their company had supplied more than two million dosage units of hydrocodone to what were allegedly Internet pharmacies in the Tampa area, despite a 2005 meeting in which DEA alerted McKesson to this specific problem.[170] The DEA told McKesson that it would therefore pursue and Order to Show Cause and an Immediate Suspension Order for its Lakeland, Florida distribution center.

In a 2007 McKesson presentation, the company noted that "abuse of prescription drugs has risen 66% since 2000," that "opioid painkillers kill more than cocaine and heroin combined" and that this is a "public health issue."[171] The presentation noted that starting May 1, 2007, McKesson would institute a "Lifestyle Drug Monitoring Program" that focused on four drugs (including

[169] Memorandum from Michael Mapes, Office of Diversion Control, to Joseph Rannazzisi, Office of Diversion Control, DEA. Meeting between office of diversion control (OD) and McKesson Corp. on January 3, 2006. Dated January 23, 2006. Exhibit 8 in De Gutierrez Mahoney deposition. Pl.1789. MCKMDL00496876.

[170] Memorandum from Michael Mapes, Office of Diversion Control, to Joseph Rannazzisi, Office of Diversion Control, DEA. Meeting between office of diversion control (OD) and McKesson Corp. on January 3, 2006. Dated January 23, 2006. Exhibit 8 in De Gutierrez Mahoney deposition. Pl.1789. MCKMDL00496876.

[171] Walker D. Lifestyle Drugs & Internet Pharmacies. McKesson, 2007. Exhibit 4 in Snider deposition. Pl.1830. MCK-WVAG-003-0001332.

oxycodone and hydrocodone), established a threshold of 8,000 dosage units, and required "due diligence" of customers exceeding that threshold.

In 2011, McKesson's director of regulatory affairs acknowledged that the company had a large number of accounts for which the oxycodone and hydrocodone thresholds were far greater than the amounts that the pharmacies actually needed, stating: "I have thought of an area that needs to be tightened up in CSMP and it is the number of accounts we have that have large gaps between the amount of Oxy or Hydro they are allowed to buy (their threshold) and the amount they really need. (Their current purchases) This increases the 'opportunity' for diversion by exposing more product for introduction into the pipeline than may be being used for legitimate purchases."[172]

In 2012, McKesson made a presentation entitled "Know Your Customer: Recognizing Regulatory and Compliance Risks."[173] The presentation explained that there was an "alarming rate of increase of prescription drug abuse beginning approximately five years ago, especially hydrocodone (Vicodin) and opioid pain drugs (Oxycontin and Oxycodone)." It noted that "27,000 died from prescription drug overdoses in 2007, a fivefold increase since 1990." It also noted that "During the same period tenfold increase in medical use of painkillers such as oxycodone

[172] Exhibit 256. MCKMDL00507799.

[173] Walker D. Know Your Customer: Recognizing Regulatory and Compliance Risks. McKesson, May 2012. Pl.1651. MCKMDL00498169

and hydrocodone." It stated that "Today number of overdose deaths involving prescription pain medication exceeds deaths from heroin and cocaine combined." The presentation also included this quote from Joseph Rannazzisi of the DEA: "The illicit pain clinics, the pharmacies that fill their scripts, and the wholesale distributors who supply pharmacies without appropriate due diligence have caused, and continue to cause, millions of dosage units of oxycodone and other controlled substances to be diverted and pose an *imminent threat to the public health and safety*" (emphasis is mine). Finally, the presentation stressed the importance of performing due diligence on prospective customers, including knowing the "volume of critical drugs – Oxycodone, Hydrocodone, Alprazalam."

Despite publicly stressing the importance of performing due diligence, in a 2012 email from Bill deGutierrez-Mahoney to senior compliance and regulatory affairs staff at McKesson, deGutierrez-Mahoney stated "we may not be following 'our own' guidelines."[174] The email intimated the concern that HDMA was announcing procedures that McKesson was not actually implementing: "Sounds to me like HDMA is signing us up to do everything that anyone thought might be relevant or a good idea…"

[174] Email from Bill deGutierrez-Mahoney to Donald Walker, et al., February 28, 2012. HDMA CSMP Guidelines. Exhibit 38 in deGutierrez-Mahoney deposition. Pl.1806. MCKMDL00545132.

In 2013, McKesson staff gave a presentation on the state of prescription drug abuse.[175] It included a slide with a graph showing a dramatic increase in opioid sales, opioid addiction treatment, and opioid deaths in the U.S. between 1999 and 2010. It noted specific examples of pill mills, internet pharmacies, and other causes of drug diversion and noted that 4.9 million people in the U.S. were abusing prescription pain relievers. It also noted that more than 45 people die every day from prescription opioid overdoses. It closed with a Voltaire quote: "With Great Power Comes Great Responsibility."

In 2014, McKesson was in possession of slides from a presentation showing that CDC had declared prescription drug overdose deaths to be an epidemic, with one death occurring every 19 minutes.[176] One of the slides noted that "The U.S. consumes 83% of the world's oxycodone and 99% of the world's hydrocodone, two highly prescribed opioid drugs for pain." It included a slide with a graph showing a dramatic increase in opioid sales, opioid addiction treatment, and opioid deaths in the U.S. between 1999 and 2010. Another slide showed that West Virginia had the highest rate of prescription drug overdose death in the nation.

[175] Boggs G. McKesson. State of Prescription Drug Abuse, September 13, 2013. Pl.851. Also Exhibit 29 in Hartle deposition.

[176] Stern F, Walker D, Boggs G, Peck K. Prescription Drug Abuse: The National Perspective. February 4, 2014. Pl.2539. MCKMDL02102775

The DEA repeatedly accused McKesson of inadequately controlling the diversion of opioid drugs.

In 2017, McKesson made certain admissions of fact under a settlement agreement with the DEA in which it acknowledged a failure to maintain effective controls against opioid diversion and agreed to pay a settlement amount of $150 million. Specifically: "McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5)."[177] These admitted failures occurred even after the company entered into a previous 2008 settlement in which the DEA alleged that the company failed to report suspicious orders of controlled substances.[178] As summarized in the 2017 settlement agreement: "In 2008, McKesson entered into a settlement agreement with the DOJ and a Memorandum of Agreement with the DEA (collectively referred to herein as the "2008 Agreements") arising out of, among other things, McKesson' s failure to report suspicious orders of controlled substances to the

[177] *Settlement Agreement and Release* between DEA and McKesson, January 17, 2017. https://www.justice.gov/opa/press-release/file/928471/download.

[178] I am not using this evidence to conclude that McKesson Corporation violated the Controlled Substances Act. I am using this evidence to establish that there were repeated allegations against the company.

DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP") in which McKesson recognized that it had a responsibility to monitor its sales of all controlled substances and report suspicious orders to the DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to the DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b)."[179]

In the orders that led to the 2008 settlement (in the amount of $13,250,000), the volume of opioids that the DEA alleged McKesson supplied to certain pharmacies was startling:

(1) In Maryland, from January 2005 through October 2006, 3 million dosage units of hydrocodone were supplied to NewCare Pharmacy in Baltimore - according to McKesson's own data, the national average amount of dispensed hydrocodone to a retail pharmacy is approximately 131,000 dosage units per year,[180] yet they allegedly sold this pharmacy an average of 1.6 million dosage units per year during this time period, more than a 12-fold difference;

[179] *Settlement Agreement and Release* between DEA and McKesson, January 17, 2017.

[180] McKesson. Understand ARCOS Data. P1.1354. MCKMDL00407449.

(2) In Texas, during an eight-month period in 2007, McKesson suppled the Mercury Drive Pharmacy and Maswoswe's Alternative Pharmacy with 2.6 million dosage units of hydrocodone, which is nearly 30 times higher than the national average; and

(3) In Florida, during one month in 2005, McKesson supplied seven pharmacies in the Tampa area with 2.1 million dosage units of hydrocodone, which is a rate 16 times higher than the national average.

Furthermore, the DEA also alleged that in spite of the 2008 settlement and McKesson's being on notice that it had a "serious and systemic" problem, no fewer than four of McKesson's distribution centers failed to report any suspicious orders to DEA for the subsequent five-year period (2008-2013) and one center reported only 16 orders as suspicious during this period.[181] The DEA noted that: "This, alone, demonstrates that it was not operating with any functional 'system to disclose' … suspicious orders of controlled substances' to DEA. … And the fact that this occurred *after* McKesson had entered into a settlement agreement with the Department of Justice and DEA in which McKesson committed to report suspicious orders makes the ensuing five-year silence particularly egregious." The

[181] Letter from DEA to Geoffrey Hobart, November 4, 2014. Exhibit 67 of Snider deposition. Pl.1443. MCKMDL00409453.

DEA concluded that "it is apparent that McKesson Aurora avoided filing of suspicious order reports by giving short shrift to supposed due diligence efforts and manipulating the monthly thresholds that were the cornerstone of McKesson's compliance program."

Among the DEA's specific allegations[182] were that:

(1) "McKesson Livonia remained silent even as it supplied 26 pharmacies that were utilized in a drug trafficking conspiracy that has since resulted in the criminal conviction of the owner of these pharmacies, Babubbai Patel, and dozens of other participants." McKesson's system to identify and disclose suspicious orders "identified none even when one of Patel's pharmacies, Preferred Care Pharmacy, for example, went from ordering less than 4,000 dosage units of hydrocodone products in March and April of 2010 to regularly ordering 16,000 dosage units a month in August 2010, to regularly ordering more than 20,000 dosage units a month in 2011. The threshold that was supposed to trigger review for suspicious ordering by McKessson Livonia instead prompted efforts by McKesson Livonia to reset this threshold to enable ever increasing hydrocodone sales. Worse, hydrocodone products constituted more than 70% of the

[182] *Id.*

controlled substances that Preferred Care Pharmacy was ordering – an obvious indicia of diversion that was, unfortunately, quite common among the Patel pharmacies and readily apparent to McKesson Livonia."[183]

(2) "McKesson Livonia saw orders of hydrocodone from People's Pharmacy in Detroit rise from less than 10,000 dosage units a month when it first came online in July 2010 to double and then triple so that it was regularly ordering more than 30,000 dosage units a month by the end of the year. McKesson Livonia's only action was to regularly raise thresholds to permit this, offering little more than 'due to increase in business' as the reason why the thresholds needed to be doubled and tripled. While McKesson Livonia was doing so, Michigan Pharmacy Board inspectors (who subsequently suspended the pharmacist's license) were able to watch from the parking lot as 'drivers' would drop off multiple 'patients' to pick up prescriptions—diversion so obvious the pharmacist readily admitted misconduct to investigators when confronted."[184]

[183] *Id.*, p. 3.

[184] *Id.*, p. 3.

(3) "McKesson's inability to instill a culture of compliance—even within its compliance operations—may explain why McKesson WCH [Washington Court House, Ohio] did not report anything suspicious about Community Drug of Manchester, Kentucky—a pharmacy in a town of less than 1,000 residents—ordering 20,000 to almost 50,000 dosage units of oxycodone products on a monthly basis in 2011."[185]

[185] *Id.*, p. 3-4.

VIII. Conclusions Regarding Supply Chain Defendants

1. Information was available to AmerisourceBergen, Cardinal Health, and McKesson to make them aware that the volume of opioids they were distributing into small communities was inconsistent with public health.
2. Information was available that oversupply of opioids inconsistent with public health was likely to result in serious, long lasting public health harm.
3. AmerisourceBergen, Cardinal Health, and McKesson oversupplied these communities, often despite access to information demonstrating that this oversupply was already occurring and was resulting in public health harm.
4. All three companies continued to oversupply even in the presence of signs of potential misuse and abuse of opioids inconsistent with public health, such as prescriptions from geographically remote pain doctors.
5. Information was available to all three companies that abuse of prescription opioids was a burgeoning public health problem and that there was a dramatic increase in the number of opioid overdose deaths.
6. All three companies continued to oversupply pharmacies in and near Cabell County with opioids, despite available information that oversupply was creating an opioid public health crisis.

7. Oversupply of opioids in and around Cabell County contributed to and created a public health hazard, with severe, long-lasting adverse public health consequences.
8. Through their oversupply of opioids, each of these companies substantially contributed to the opioid epidemic in Cabell County, West Virginia and the resulting harms to public health.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed in Boston, MA on August 2, 2020.

Michael Siegel

MICHAEL SIEGEL,

Appendix A

All references listed in the Report and other related materials

City of Huntington v. AmerisourceBergen Drug Corp. et al., No. 3:17-cv-1362 (S.D.W. Va.); *Cabell County Commission v. AmerisourceBergen Drug Corp. et al.*, No. 3:17-cv-1665 (S.D.W. Va.)

Prepared for:
Plaintiffs' Steering Committee
In Re: National Prescription Opiate Litigation MDL 2804

BATES

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1/1/2012	Department of Health and Human Services		Drug Diversion in the Medicaid Program State Strategies for Reducing Prescription Drug Diversion in Medicaid
3/30/2016	Drug Safety and Risk Management Advisory Committee		Briefing Book for The Extended-Release and Long-Acting (ER/LA) Opioid Analgesic Risk Evaluation and Mitigation Strategy
1/1/2002	Drug Enforcement Agency		Review of the Drug Enforcement Administration's Investigations of the Diversion of Controlled Pharmaceuticals, Report Number I-2002-010
12/1/2003	Government Accountability Office		PRESCRIPTION DRUGS OxyContin Abuse and Diversion and Efforts to Address the Problem GAO-04-110
7/1/2006	Department of Justice		Follow-Up Review of the Drug Enforcement Administration's Efforts to Control the Diversion of Controlled Pharmaceuticals -I-2006-004
8/1/2011	Government Accountability Office		Prescription drug control -DEA Has Enhanced Efforts to Combat Diversion, But could better assess and report program results- GAO-11-744

2/1/2015	Government Accountability Office		GAO-15-202, GAO report to congressional requesters - Drug Shortages, Better management of the quota process for controlled substances Needed; coordination between DEA and FDA should be improved
5/5/2015	Government Accountability Office		GAO-15-494T -testimony before the senate caucus on international narcotics control US Senate. Controlled substances DEA needs to better manage its quota process and improve coordination with FDA
6/1/2015	Government Accountability Office		GAO-15-471, report to congressional requesters, Prescription Drugs-more DEA information about registrants controlled substances roles could improve their understanding and help ensure access
5/1/2016	Government Accountability Office		GAO-16-310-report to congressional requests -Controlled Substances, DEA should take additional actions to reduce risks in monitoring the continued eligibility of its registrants
6/22/2016	Government Accountability Office		GAO-16-737T -Testimony before the committee on the judiciary US Senate, DEA additional Actions Needed to address prior GAO recommendations
12/1/2003	Material Handling & Logistics		HDMA Voluntary Guidelines Released MH & L Staff
1/1/2013	Department of Justice		Drug Enforcement Administration Office of Diversion Control ODG/ Regulatory Section - Effective Controls Against Diversion
9/1/2016	Attorney General of Massachusetts		CVS Pharmacy to Strengthen policies around dispending opioids and require use of prescription monitoring program in groundbreaking settlement
10/14/2010	US Attorney's Office Central District of California		CVS admits illegally selling pseudoephedrine to criminals who made methamphetamine, agrees to pay $77.6 million to resolve government investigation

1/17/2017	Department of Justice		Department of Justice, U.S. Attorney's Office, Middle District of Florida, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs
1/17/2017	Department of Justice		Department of Justice, U.S. Attorney's Office, District of Massachusetts, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs
1/17/2017	Department of Justice		Department of Justice, Office of Public Affairs, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs
1/17/2017	Department of Justice		Department of Justice, U.S. Attorney's Office, Central District of California, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs
1/17/2017	US Attorney's Office Central District of California		Department of Justice, U.S. Attorney's Office, Eastern District of California, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs
1/17/2017	US Attorney's Office District of Colorado		Department of Justice, U.S. Attorney's Office, District of Colorado, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs
1/17/2017	US Attorney's Office District of New Jersey		Department of Justice, U.S. Attorney's Office, District of New Jersey, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs
1/17/2017	US Attorney's Office Northern District of West Virginia		Department of Justice, U.S. Attorney's Office, Northern District of West Virginia, McKesson Agrees to Pay Record $150 Million Settlement for

			Failure to Report Suspicious Orders of Pharmaceutical Drugs
1/17/2017	US Attorney's Office Western District of Wisconsin		Department of Justice, U.S. Attorney's Office, Western District of Wisconsin, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs
7/9/2018	Purdue Pharma		BUTRANS -buprenorphine patch, extended release Purdue Pharma
11/16/2013	Department of Justice		Prescription drug trafficking and abuse trends, Pharmacy diversion Awareness conference Louisville, KY
12/1/2011	Center for Disease Control		CDC National centers for health statistics data brief number 81
9/24/2013	Department of Justice		Doctor sentenced for running pill mill and contributing to death
9/20/2013	Department of Justice		New York Methodist Hospital agrees to implement compliance program to settle civil claims under the controlled substances act
9/1/2017	Wexler	Chuck	The Unprecedented Opioid Epidemic: As Overdoses Become a Leading Cause of Death, Police, Sheriffs, and Health Agencies Must Step Up Their Response
6/3/2014	U.S. Attorney's Office Northern District of West Virginia		Pharmacist Charged with Illegal Distribution of Painkillers
10/27/1970	US Law		Controlled Substances Act, Title 21 - Food and Drugs, Chapter 13 - Drug Abuse Prevention and Control, Subchapter I - Control and Enforcement
7/2/2018	US Census Bureau		United States Census Bureau, Community Facts - Find popular facts (population, income, etc.) and frequently requested data about your community, Williamson City, West Virginia, Veterans

7/2/2018	US Census Bureau		United States Census Bureau, Community Facts - Find popular facts (population, income, etc.) and frequently requested data about your community, Williamson City, West Virginia, Population
2013	McKesson		Photograph of pill mill
12/14/1910	Hathitrust.org		Importation and use of opium. Hearings before the Committee on Ways and Means of the House of Representatives, 61st Congress, 3d session on H.R. 25240, H.R. 25241, H.R. 25242, and H.R. 28791, December 14, 1910 and January 11, 1911
7/10/2018	Center for Disease Control		Multiple Cause of Death, 1999-2016 Charts, Rx Opioid deaths, Deaths by Year
7/10/2018	Center for Disease Control		Multiple Cause of Death, 1999-2016 Results, Rx Opioid Deaths
7/26/2017	McKesson		McKesson 2017 Annual Meeting of Stockholders and Proxy Statement
1/1/2017	Mallinckrodt.com		Exalgo (gydromorphone HCI) extended-release tablets, CII 8 mg
9/24/2013	Department of Justice		Pasco County Pharmacist sentenced for illegally distributing pain medications
7/19/2018	Deposition Exhibit		Photograph of Michael Oriente
7/19/2018	Deposition Exhibit		Photo of Dales Pharmacy Exterior
10/6/2012	Deposition Exhibit		Photo of Dales Pharmacy
7/19/2018	Deposition Exhibit		Photo of Dales Pharmacist Huy Duong
3/20/2018	Energycommerce.house.gov		Press release: Suboversight Presses DEA for answers to bipartisan E&C investigation into alleged pill dumping in West Virginia
7/13/2018	Drug Enforcement Administration		DEA Current Online, FAQ's -Fentanyl and Fentanyl -Related Substances
6/1/2016	Drug Enforcement Administration		DEA targets Fentanyl - a real threat to law enforcement
12/22/2016	Department of Justice		TEVA Pharmaceutical industries agrees to pay more than $283 million to resolve foreign corrupt practice charges

7/18/2013	Department of Justice		DOJ Pharmaceutical Company Agrees to Pay $3.5 Million to Settle False Claims Act Allegations
9/29/2008	Department of Justice		DOJ Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing
7/16/2018	Deposition Exhibit		Photograph of Heroin vs. Fentanyl
12/19/2018	Energy and Commerce Committee		Energy & Commerce Report Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia
4/24/2007	Drug Enforcement Administration		DEA Suspends Orlando Branch of Drug Company from Distributing Controlled Substances
7/18/2017	Drug Enforcement Administration		Press Release Safeway Pharmacies Pay $3 Million to Resolve Allegations Chain Failed to Timely Report Drug Diversion
6/11/2013	Drug Enforcement Administration		Walgreens Agrees to Pay A Record Settlement of $80 Million for Civil Penalties Under the Controlled Substances Act
12/11/2007	Drug Enforcement Administration		DEA Suspends Lakeland Branch of Drug Company From Distributing Controlled Substances
5/15/2012	Drug Enforcement Administration		DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility
9/10/2018	US Census Bureau		Census Data Quick Facts Sanford City, Florida
4/20/2015	Federal Trade Commission		Cardinal Health Agrees to Pay $26.8 Million to Settle Charges It Monopolized 25 Markets for the Sale of Radiopharmaceuticals to Hospitals and Clinics
12/23/2016	Department of Justice		United States Reaches $34 Million Settlement with Cardinal Health for Civil Penalties Under the Controlled Substances Act
4/21/2011	Department of Justice		Ohio-Based Cardinal Health Inc. to Pay $8 Million to Resolve False Claims Act Allegations

7/26/2007	Securities and Exchange Commission		SEC Sues Cardinal Health, Inc. for Fraudulent Earnings and Revenue Management Scheme, Pharmaceutical Distribution Company to Pay $35 Million Penalty
6/7/2015	Healthcare Distribution Management Association		2015 Business and Leadership Conference Attendee List by Individual
12/23/2016	Department of Justice		DOJ Manhattan U.S. Attorney Announces $10 Million Civil Penalty Recovery Against New York Pharmaceutical Distributor Kinray, LLC
2/6/2012	Department of Justice		DEA Suspends Pharmaceutical Wholesale Distributor and Retailers' Ability to Sell Controlled Substances, Recent Efforts Go Beyond "Mom and Pop" Businesses
11/18/2010	Cardinal Health		Cardinal Health to Acquire Kinray for $1.3 Billion, Increases Cardinal Health's Retail Independent Pharmacy Customer Base by 40 Percent
12/26/2006	ag.ny.gov		Article with attachments: State Reaches Agreement with Cardinal on Drug Trading Issues
5/8/2018	Cardinal Health		Testimony of George S. Barrett, Executive Chairman, Cardinal Health; Hearing before the United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations
7/1/2011	Florida Department of Health		State Surgeon General Declares Public Health Emergency Regarding Prescription Drug Abuse Epidemic, Declaration requires practitioners to dispose of controlled substance inventory
4/24/1971	US Law		21 C.F.R. Section 1301.74 Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances Security Requirements

5/10/2007	Department of Justice		The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin; Will Pay Over $600 Million
1/30/2018	macrotrends.net		AmerisourceBergen Revenue 2006-2018 ABC
1/16/2018	New Mexico Region HIDTA		Opioids: The Face of the Demon in New Mexico
9/28/2018	AmerisourceBergen		Corporate integrity agreement between the office of inspector general of the department of health and human services and AmerisourceBergen corporation
10/1/2018	Food and Drug Administration		October 1, 2018: AmerisourceBergen Corp. to Pay $625 Million to Settle Civil Fraud Allegations Resulting from Its Repackaging and Sale of Adulterated Drugs and Unapproved New Drugs, Double Billing and Providing Kickbacks
6/24/2008	Drug Enforcement Administration		Remarks by Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, before the House Judiciary Committee Subcommittee on Crime, Terrorism, & Homeland Security
4/7/2014	Department of Justice		Department of Justice, Statement of Joseph T. Rannazzisi before the Subcommittee on Health Committee on Energy and Commerce U.S. House of Representative for a hearing entitled "Improving Predictability and Transparency in DEA and FDA Regulation" presented on April 7, 2014
12/20/2017	West Virginia Department of Health & Human Resources		2016 West Virginia Overdose Fatality Analysis, Healthcare Systems Utilization, Risk Factors, and Opportunities for Intervention
1/1/2018	Fein	Adam	2016 MDM Market Leaders / Top Pharmaceuticals Distributors
1/1/2018	fortune.com		Fortune 500 2017 Top 20

11/1/2018	Hedegaard	Holly	NCHS Data Brief, No. 329, November 2018, Drug Overdose Deaths in the United States, 1999-2017
1/10/2019	United States Census Bureau		United Status Census Bureau, Oceana Town, West Virginia
4/25/2013	FBI.gov		FBI Press Release: Washington, D.C. Doctor Indicted on Prescription Drug Distribution Charges
8/23/2017	Department of Justice		Beckley area physician sentenced to 20 years in federal prison for oxycodone crime
4/21/2016	Department of Justice		Charleston Doctor pleads guilty to Federal crime involving dispensing fentanyl
2/20/2018	Department of Justice		U.S. Attorney announces 69-count indictment charging owners, managers and physicians associated with Hope Clinic
10/27/2010	Department of Justice		Department of Justice -DEA East Main Street Pharmacy Affirmance of Suspension Order
4/16/1996	Drug Enforcement Agency		Diversion Investigators Manual 04/16/1996
11/1/2019	ARCOS		AmerisourceBergen Drug 12 Opioid Distribution into Cabell County, WV by Drug
2006-2014	ARCOS		Opioid Shipments to Pharmacies in Cabell County, WV 2006-2014
2006-2014	ARCOS		Opioid Shipments to Pharmacies in Wyoming County, WV 2006-2014
2006-2014	ARCOS		12 Opioid Drug Total Dosage Units by Company in Cabell County, WV
5/8/2018	Energy and Commerce Committee		Collis Quote 3: Congressional Testimony
5/8/2018	Energy and Commerce Committee		Collis Quote 2: Congressional Testimony
5/8/2018	Energy and Commerce Committee		Collis Quote 1: Congressional Testimony
5/8/2018	Energy and Commerce Committee		Combating the Opioid Epidemic Examining Concerns About Distribution and Diversion; House of Representatives Subcommittee on Oversight and Investigations Committee on Energy and Commerce

5/29/2020	Deposition Exhibit		Photo of Safescript Pharmacy # 6
10/27/1970	US Law		Title 21 United States Code Controlled Substances Act Subchapter 1 Control and Enforcement Part A - Introductory Provisions (2) the illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people
6/14/1943	United States Supreme Court		Supreme Court of the United States v. Direct Sales Co
2006-2014	ARCOS		Oxycodone and Hydrocodone Shipments to Drug Emporium in Cabell County and Huntington City, WV
2006-2014	ARCOS		Oxycodone and Hydrocodone Shipments to McCloud Family Pharmacy in Cabell County and Huntington City, WV
7/1/2013	Film		Oxyana.mp4
2006-2014	ARCOS		Opioid Shipments to [redacted] by Distributor 2006-2012, Safescript Pharmacy #6
7/19/2018	Deposition Exhibit		Pill Mountain
7/8/2008	Ohio State BOP		Minutes of the July 7-8, 2008 Meeting of the Ohio State Board of Pharmacy
8/26/2015	The General Assembly or PA		The General Assembly of Pennsylvania House Bill No. 1511 Session of 2015

DEPOSITIONS

Michael Oriente 07/19/2018 Deposition and Exhibits
Nathan Hartle 07/31/2018 Deposition and Exhibits
Nathan Hartle 08/01/2018 Deposition and Exhibits
Steve Reardon 11/30/2018 Deposition and Exhibits
Eric Brantley 11/27/2018 Deposition and Exhibits
David Gustin 08/17/2018 Deposition and Exhibits

Eugene Cavacini 01/25/2018 Deposition and Exhibits
Bill de Gutierrez-Mahoney 11/28/2018 Deposition and Exhibits
Gary Hilliard 01/10/2019 Deposition and Exhibits
Blaine Snider 11/08/2018 Deposition and Exhibits
Donald Walker 01/10/2019 Deposition and Exhibits
John Gray 07/30/2020 Deposition and Exhibits
Lisa Mash 07/28/2020 Deposition and Exhibits
Patrick Kelly 05/10/2019 Deposition and Exhibits

EXPERTS

David Kessler 03/26/2019 Expert Report and Supporting Documentation
James E. Rafalski 04/15/2019 Expert Report and Supporting Documentation
James E. Rafalski 08/03/2020 Expert Report and Supporting Documentation
David T. Courtright 03/21/2019 Expert Report and Supporting Documentation
Thomas McGuire 03/25/2019 Expert Report and Supporting Documentation
Matthew Perri III 03/25/2019 Expert Report and Supporting Documentation
Seth B. Whitelaw 04/15/2018 Expert Report and Supporting Documentation
Jane C. Ballantyne 03/25/2019 Expert Report and Supporting Documentation
Jane C. Ballantyne 03/25/2019 Exhibit B - Ballantyne Materials Considered
Catherine Rahilly-Tierney, M.D., M.P.H. 05/10/2019 Expert Report and Supporting Documentation
Catherine Rahilly-Tierney, M.D., M.P.H. 02/03/2020 Expert Report and Supporting Documentation
Craig J. McCann 03/25/2019 Expert Report and Supporting Documentation
Craig J. McCann 08/03/2020 Expert Report and Supporting Documentation CT2 Additional Expert Report Figures and Charts - Appendix 12

PLEADINGS

1/5/2017	Settlement Agreement and Release between DOJ, DEA and McKesson
4/30/2008	Settlement Agreement between USDOJ and McKesson
3/18/2011	Administrative Memorandum of Agreement between DOJ, DEA and Walgreen Co.
4/5/2013	Settlement and Memorandum of Agreement between DOJ, DEA and Walgreen Co.

9/27/2017	Settlement Agreement, DOJ, OIG-HHS, HHS, DHA, OMP, FEHBP, VA, ABSG, ABDC, OSC, MII, ABC Defendants
6/29/2017	West Virginia Board of Medicine. Consent Order. In Re: James Edwin Prommersberger, D.P.M. June 29, 2017.
3/7/2012	Cardinal Health, Inc. v. Eric H. Holder, Civil Action No. 2012-0185 (D.D.C. 2012), District Court, District of Columbia (Filed: March 7th, 2012)
5/14/2012	Administrative Memorandum of Agreement between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Cardinal Health, Inc.
12/7/2017	Steinberg Verified Shareholder Derivative Complaint
8/1/2017	Miami-Luken, Inc. vs. US Department of Justice, Drug Enforcement Administration, Report and Recommendation
2/10/2012	Declaration of Joseph Rannazzisi - Cardinal Health v, Holder
5/29/2018	Defendant McKesson Corporation's Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-26)
8/18/2009	United States v. $65,806.86, More or Less, In United States Currency, Civil Action No. 2:09-cv-0944, USDC Southern District of West Virginia, Charleston
1/21/2016	Amended Complaint - State of West Virginia ex rel. Patrick Morrisey et al v. McKesson Corporation
2/18/2014	In the Circuit court of Mingo County West Virginia Civil action No.:10-C-251 v. Tug Valley Pharmacy
6/2/2014	NO. 14-0144 In the Supreme Court of Appeals of West Virginia Tug Valley Pharmacy v. All Plaintiffs Below in Mingo County Civil actions
6/2/2014	Tug Valley Pharmacy, et al v. Plaintiffs in Mingo County Civil Actions, Respondents' Brief
5/9/2012	Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc.
2/10/2012	Declaration of Joseph Rannazzisi
2/10/2012	Cardinal Health, Inc. v. Holder, Attachment 6 to Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction; Top 25 Distributors Located in Florida selling Oxycodone products to all retail level registrants in the State of Florida, January - December 2010
2/10/2012	Cardinal Health, Inc. v. Holder, Attachment 7 to Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction; Top 25 Distributors Located in Florida selling Oxycodone products to all retail level registrants in the State of Florida, January - December 2011
2/10/2012	Cardinal Health, Inc. v. Holder, Attachment 8 to Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction; DEA Order to Show Cause and Immediate Suspension of Registration in the matter of Cardinal Health dated November 28, 2007

2/10/2012	Cardinal Health, Inc. v. Holder, Attachment 9 to Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction; DEA Order to Show Cause and Immediate Suspension of Registration in the matter of Cardinal Health dated December 5, 2007
2/10/2012	Cardinal Health, Inc. v. Holder, Attachment 10 to Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction, DEA Order to Show Cause and Immediate Suspension of Registration in the matter of Cardinal Health dated December 7, 2007
2/10/2012	Cardinal Health, Inc. v. Holder, Attachment 11 to Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction, DEA Order to Show Cause in the matter of Cardinal Health dated January 30, 2008
10/2/2008	Cardinal Health, Inc. v. Holder, Attachment 12 to Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction, Settlement and Release Agreement and Administrative Memorandum of Agreement between US DOJ, DEA and Cardinal Health, Inc., dated October 2, 2008
2/10/2012	Cardinal Health, Inc. v. Holder, Attachment 15 to Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction, DEA Order to Show Cause and Immediate Suspension of Registration in the matter of Cardinal Health, dated February 2, 2012
2/10/2012	Cardinal Health, Inc. v. Holder, Attachment 17 to Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction, Chart of Sales to Pharmacies in Sanford, Florida
2/10/2012	Cardinal Health, Inc. v. Holder, Attachment 48 to Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction, DEA Letter to Cardinal Health in reference to registration [redacted]
7/27/2018	Cardinal Health Letter re. document production sent to Liaison Counsel for Plaintiffs, Manufacturer Defendants, Distributor Defendants, Chain Pharmacy Defendants, and Physician Defendants re: National Prescription Opiate Litigation, MDL No. 2804
12/22/2016	United States of America v. Kinray, LLC, Consent Order
10/1/2017	Letter re: please vote for the independent chair proposal at cardinal health November 8, 2017
9/27/2017	United States of America against AmerisourceBergen Specialty Group, LLC, Information
9/27/2017	United States of America against AmerisourceBergen Specialty Group, LLC, Plea Agreement
2/1/2018	Letter to AmerisourceBergen Shareholders re: vote three resolutions at annual meeting on March 1, 2018
1/28/2014	United States of America v. Alen Johannes Salerian, Opinion and Order, Case No. 1:13CR00017
10/14/2008	Before the Board of Medicine, In Re: David Lee Morgan, D.O., License No.: [redacted], Consent Order

4/19/2017	United States of America v. City Pharmacy, LLC, et al, Order on Defendant David M. Wasanyi's Motion to Dismiss and Motion to Strike Expert Testimony and Granting in part and denying in part Government's Motion for Summary Judgment
2/15/2018	United States of America v. James H. Blume, Jr., D.O, et al., Indictment Count One (Conspiracy to Distribute and Dispense Oxycodone)
7/31/2019	The State of Oklahoma's Response to Defendants' Renewed Motion for Judgment (Oklahoma Findings of Facts and Conclusions of Law)
6/13/2019	Joint and Third Amended Complaint filed by Cabell County and City of Huntington, WV
9/27/2006	Letter from CAH Counsel to NYAG
6/28/2019	Plaintiff's Memorandum of Law in Support of Motion for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties Under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them (Corrected) June 28, 2018
5/7/2001	Howard Engle v Philip Morris et al. Circuit Court of the 11th Judicial Circuit, Dade County FL, General Jurisdiction Division (Case No. 94-08273 CA).
6/23/2020	Discovery Ruling 9: Order denying defendants' motion to compel discovery responses on opioid-related expenditures. United States District Court for the Southern District of West Virginia, June 23, 2020.

Appendix B

CURRICULUM VITAE

Michael B. Siegel, MD, MPH

CURRICULUM VITAE

Michael B. Siegel, MD, MPH

Professor
Boston University School of Public Health
Department of Community Health Sciences
801 Massachusetts Avenue, 4th Floor, Boston, MA 02118
mbsiegel@bu.edu (617) 358-1347

Education

1. University of California at Berkeley/UCSF
   General Preventive Medicine Residency Program
   August, 1991 to June, 1993
   M.P.H. completed: May, 1992 (Epidemiology)

2. Berkshire Medical Center, Pittsfield, MA
   PGY-1 Year in Internal Medicine
   July, 1990 to June, 1991

3. Yale University School of Medicine
   M.D. completed: May, 1990

4. Brown University
   B.A., Environmental Studies: May, 1986
   Magna cum laude, Phi Beta Kappa, Sigma Xi

Employment Experience

February 2005 to present:
Boston University School of Public Health
Department of Community Health Sciences (formerly Social and Behavioral Sciences Department)
Professor

September 1999 to February 2005:
Boston University School of Public Health
Social and Behavioral Sciences Department
Associate Professor

August, 1995 to September, 1999:
Boston University School of Public Health
Social and Behavioral Sciences Department
Assistant Professor

July, 1993 to July, 1995:
Office on Smoking and Health
Centers for Disease Control and Prevention, Atlanta, GA
Epidemiology fellowship (EIS program)

July, 1991 to May, 1993:
Santa Clara County Health Department
Bureau of Alcohol and Drug Programs
San Jose, CA
Part-time physician for methadone maintenance program

Summers, 1983-1986:
Danbury Health Department, Danbury, CT
Section of Environmental and Occupational Health
Intern

Awards and Honors

- Boston University School of Public Health Excellence in Teaching Award, Fall, 1996
(SB733: Mass Communication and Public Health)

- Boston University School of Public Health Excellence in Teaching Award, Spring, 1998
(SB815: Program Evaluation Research)

- Boston University School of Public Health Excellence in Teaching Award, Summer, 1999
(SB815: Program Evaluation Research)

- Boston University School of Public Health Excellence in Teaching Award, Fall, 1999
(SB733: Mass Communication and Public Health)

- Norman A. Scotch Award for Excellence in Teaching, 2001
(presented to the outstanding teacher of the year at Boston University School of Public Health)
Presented at Commencement exercises, May 20, 2001

- Co-author of paper selected by American Marketing Association Advertising Special Interest Group as best advertising article written in 1996 (Pollay RW, Siddarth S, Siegel M, Haddix A, Merritt RK, Giovino GA, Eriksen MP: The last straw? Cigarette advertising and realized market shares among youths and adults, 1979-1993. Journal of Marketing 1996; 60:1-16)

- Boston University School of Public Health Excellence in Teaching Award, Fall, 2001 (SB733: Mass Communication and Public Health)
- Recipient of a Flight Attendant Medical Research Institute (FAMRI) Distinguished Professor Award, July 1, 2002 – June 30, 2005
- Boston University School of Public Health Excellence in Teaching Award, Fall, 2003 (SB733: Mass Communication and Public Health)
- Boston University School of Public Health Excellence in Teaching Award, Spring, 2005 (SB860: Strategies for Public Health Advocacy)
- Boston University School of Public Health Excellence in Teaching Award, Summer, 2005 (SB822: Quantitative Methods for Program Evaluation)
- Boston University School of Public Health Excellence in Teaching Award, Spring, 2007 (SB860: Strategies for Public Health Advocacy)
- Boston University School of Public Health Excellence in Teaching Award, Fall, 2007 (SB733: Mass Communication and Public Health)
- Boston University School of Public Health Excellence in Teaching Award, Spring, 2009 (SB860: Strategies for Public Health Advocacy)
- Boston University School of Public Health Excellence in Teaching Award, Fall, 2009 (SB733: Mass Communication and Public Health)
- Boston University School of Public Health Educational Innovation Award, 2010 Presented at the 5th Annual John McCahan Medical Campus Education Day, June 11, 2010
- Boston University School of Public Health Excellence in Teaching Award, Fall, 2010 (SB721: Social and Behavioral Sciences for Public Health)
- Boston University School of Public Health Excellence in Teaching Award, Spring, 2011 (SB721: Social and Behavioral Sciences for Public Health)
- Boston University School of Public Health Excellence in Teaching Award, Spring, 2011 (SB860: Strategies for Public Health Advocacy)
- Boston University School of Public Health Excellence in Teaching Award, Spring 2015 (SB721: Social and Behavioral Sciences for Public Health)

- 2019 Lifetime Achievement Award, American Public Health Association, Section on Alcohol, Tobacco, and Other Drugs

Books

Siegel M, Doner L. *Marketing public health: Strategies to promote social change*. Gaithersburg, MD: Aspen Publishers, Inc.; 1998.

Doner L, Siegel M. *Marketing public health: Strategies to promote social change (2nd edition)*. Sudbury, MA: Jones & Bartlett Publishers, Inc.; 2007.

Resnick E, Siegel M. *Marketing public health: Strategies to promote social change (3nd edition)*. Sudbury, MA: Jones & Bartlett Learning; 2012.

Publications

1. Nakabayashi K, Aronson SC, Siegel M, Stunner WQ, Aronson SM: Traffic fatalities in Rhode Island: Part I -- Descriptive epidemiology. Rhode Island Medical Journal 1984; 67:25-30.

2. Nakabayashi K, Aronson SC, Siegel M, Sturner WQ, Aronson SM: Traffic fatalities in Rhode Island: Part II -- The timing of accidents and the role of marital status, alcohol, and psychoactive drugs. Rhode Island Medical Journal 1984; 67:171-178.

3. Nakabayashi K, Aronson SC, Siegel M, Sturner WQ, Aronson SM: Traffic fatalities in Rhode Island: Part III -- The role of the motorcycle. Rhode Island Medical Journal 1984; 67:453-459.

4. Aronson SC, Nakabayashi K, Siegel M, Sturner WQ, Aronson SM: Traffic fatalities in Rhode Island: Part IV -- The pedestrian victim. Rhode Island Medical Journal 1984;67:485-489.

5. Siegel M, Forsyth B, Siegel L, Cullen MR: The effect of lead on thyroid function in children. Environ Res 1989; 49:190-196.

6. Yakovlevitch M, Siegel M, Hoch D, Rutlen D: Pulmonary hypertension in a patient with tryptophan-induced eosinophilia-myalgia syndrome. Am J Med 1991; 90:272-3.

7. Siegel M: Smoking and leukemia: Evaluation of a causal hypothesis. Am J Epidemiol 1993; 138:1-9.

8. Siegel M: Involuntary smoking in the restaurant workplace: A review of employee exposure and health effects. JAMA 1993; 270:490-493

9. Siegel M: Re: Smoking and leukemia: evaluation of a causal hypothesis (reply to letter to editor). Am J Epidemiol 1994; 139:852.

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Published Reports, Columns, Op-Eds, Book Chapters, and Letters

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2. Siegel M. Second-hand smoke (letter to editor). The Toronto Globe and Mail 1996; June 10.

3. Siegel M. Secondhand smoke: Fact & fiction. Massachusetts Association of Health Boards Quarterly 1996; 14:1,6,7.

4. Siegel M. Tobacco: The $10 billion dollar debate (op-ed column). The Washington Post 1996; December 22:C7.

5. Siegel M. What sort of tobacco settlement? (op-ed column). The Washington Post 1997; May 4:C7.

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9. Siegel M. Outrage of the Month: American Cancer Society and American Heart Association - Failing to oppose a tobacco deal. Health Letter 1998 (May), Volume 14, Number 5. Washington, DC: Public Citizen, Health Research Group.

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14. Siegel M. Tobacco Industry Sponsorship in the United States, 1995-1999. Boston, MA: Boston University School of Public Health, 2000. http://dcc2.bumc.bu.edu/tobacco.

15. Biener L, Siegel MB. The role of tobacco advertising and promotion in smoking initiation. In: U.S. Department of Health and Human Services. Changing Adolescent Smoking Prevalence: Where It Is and Why (Smoking and Tobacco Control Monograph 14). Bethesda, MD: National Institutes of Health, National Cancer Institute, NIH Publ. No. 02-5086, November 2001, pp. 201-212 (Chapter 13).

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24. Siegel M. Smoking ordinance will backfire (letter to the editor). The Acorn (Agoura Hills, CA), January 31, 2008.

25. Siegel M. There's no room for racist nicknames in Natick (op-ed). The Metrowest Daily News, February 12, 2008.

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28. Siegel M. Tobacco regulations are no regulations at all: A proposal to put cigarettes under FDA supervision is so limited that it's really a smoke screen for Big Tobacco (op-ed). The Los Angeles Times 2009; June 3.

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49. Siegel M. Gun control, another place where race matters: Firearm policy may have different effects on homicide rates of white and black Americans (op-ed). BU Today, June 17, 2016.

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57. Siegel M. How the US firearms industry influences gun culture, in 6 charts. The Conversation, February 23, 2018.

58. Pahn M, Knopov A, Siegel M. Second Amendment not a license to kill (op-ed). Memphis Commercial Appeal, March 13, 2018.

59. Siegel M. Should the government ban e-cigarettes (op-ed)? BU Today, September 17, 2018.

60. Rothman EF, Bair-Merritt M, Siegel M, Zeoli A. Intimate partner violence. In: Preventing Gun Violence (APHA Handbook) (in press).

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68. Siegel M. FDA should regulate e-cigarettes to limit access to youths (op-ed). Rome News-Tribune, September 18, 2019.

69. Siegel M. FDA should regulate e-cigarettes to limit access to youths (op-ed). Inside Sources, September 23, 2019.

70. Siegel M. Limit e-cigs' access to youths (op-ed). Jacksonville Journal Courier, September 25, 2019.

71. Siegel M. California is targeting vaping. Why aren't youth alcohol and cigarette use also in the crosshairs? (op-ed). Los Angeles Times, September 25, 2019.

72. Siegel M. Perspective: We don't know: CDC lacks key answers about vaping lung injuries (op-ed). Healio, September 26, 2019.

73. Siegel M, Boine C. Dear Governor: THC, not e-cigarettes, is the problem (op-ed). Springfield Republican, October 4, 2019.

74. Siegel M. Regulate, but don't ban, flavored e-cigarettes (op-ed). The Hill, October 18, 2019.

75. Siegel M. Oregon regulators misleading public with overbroad targeting of e-cigarettes (op-ed). The Oregonian, October 28, 2019.

76. Siegel M. Commentary: E-cig panic made things worse (op-ed). The Orangeburg Times & Democrat, May 22, 2020.

Presentations at Scientific/Professional Meetings

1. Involuntary smoking in the restaurant workplace: evaluation of exposure and health effects (poster). Prevention '93 Conference, St. Louis, MO, April, 1993.

2. Panel member and presenter on the effectiveness of tobacco control policies and the role of local tobacco control policies. National Cancer Institute ASSIST training course, Washington, DC, December 2, 1993.

3. Panel member and presenter on the role of government in tobacco control and the effects of preemption on protection of the public from environmental tobacco smoke exposure. California Preemption Education Conference, The Wellness Foundation, San Diego, CA, October 2-3, 1994.

4. Mannino D, Siegel M, Husten C, Rose D, Etzel R. Environmental tobacco smoke exposure and respiratory diseases in children (abstract). Scientific Highlights: Abstracts of Original Investigations. The 60th Annual International Scientific Assembly of the American College of Chest Physicians. *Chest* 1994; 106:115S.

5. The effects of separately ventilated smoking lounges on the health of smokers: Is this an

appropriate public health policy? Epidemiology Grand Rounds, CDC, November 8, 1994.

6. Panel member and presenter on evaluation of public health programs. Chronic Disease Conference, National Center for Health Promotion and Disease Prevention, CDC, Washington, DC, December 7-9, 1994.

7. The impact of cigarette advertising on brand market share among adults and adolescents (poster). EIS Conference, CDC, Atlanta, GA, March, 1995.

8. Giovino GA, Siegel M, Tomar SL. Cigarette advertising and brand preference among adolescents and adults: data from U.S. national studies. Paper presented at the 1995 Society for Consumer Psychology Conference: The Role of Advertising in Social Marketing, Atlanta, GA, May 18, 1995.

9. Panel member and presenter on preemption and its effect on public health. National Tobacco Control Conference, Boston, MA, June 2-4, 1995.

10. Faculty member. Tobacco Control Summer Institute, University of North Carolina, July 16-21, 1995. Co-coordinator of course on clean indoor air policy.

11. Speaker. Protecting Youth from Tobacco Conference. Andover, MA, September 21, 1995.

12. Speaker and panelist. Tobacco and the Latino Community seminar, Latino Health Institute. Boston University School of Public Health, October 10, 1995.

13. Workshop leader and presenter. Tobacco Prevention: Connecting for the Future (ASSIST Information Exchange Training). Washington, DC, October 17, 1995.

14. Organizer/guest speaker. Symposium on the Public Health Problem of Environmental Tobacco Smoke Exposure in Restaurants. Boston University School of Public Health, November 13, 1995.
15. The Power of Mass Communication to Promote Health. Boston University School of Public Health, Public Health Forum, January 30, 1996.

16. Pollay RW, Siddarth S, Siegel M. Realized market shares among old and new smokers and advertising share of voice. Conference of the American Academy of Advertising, Vancouver, British Columbia, March 29-April 1, 1996.

17. Speaker. Boston University School of Medicine Cancer Prevention and Control Grand Rounds, May 17, 1996.

18. Pollay RW, Siddarth S, Siegel M. Cigarette advertising and realized market shares among mature and immature smokers. Marketing and Public Policy Conference, Washington, DC, May 17-18, 1996.

19. Workshop leader and presenter. National Tobacco Control Conference, Chicago, IL, May 29-30, 1996.

20. Keynote speaker. Massachusetts Tobacco Control Conference. Marlboro, MA, June 3, 1996.

21. Course coordinator, "Clean Indoor Air Policies," Tobacco Control Summer Institute, St. Louis, MO, July 8-12, 1996.

22. Workshop leader and presenter. The 1st Annual Conference on Local Control, Chicago, IL, November 15-16, 1996.

23. Siegel M, Connolly G, Celebucki C, Skandera M. Does cigarette advertising in magazines target youths? Presented at the 124th Annual Meeting of the American Public Health Association, New York, NY, November 17-21, 1996.

24. Siegel M, Barnes E, Kot V, Osthimer B. The societal costs of welfare "reform": Homelessness and its public health consequences. Presented at the 124th Annual Meeting of the American Public Health Association, New York, NY, November 17-21, 1996.

25. Pucci L, Siegel M. Does tobacco advertising target adolescents? The nature of stationary outdoor tobacco advertising in six Boston neighborhoods. Presented at *Prevention 97*, March 19-20, 1997, Atlanta, GA.

26. Siegel M. Global tobacco settlement: Public health victory or resounding defeat? Preventive Medicine Grand Rounds, Carney Hospital, Dorchester, MA, September 23, 1997.

27. The Tobacco Settlement: The Thrill of Victory or the Agony of Defeat? Boston University School of Public Health, Public Health Forum, October 14, 1997.

28. The Societal Costs of Welfare "Reform." Boston University School of Public Health, Public Health Forum, April 7, 1998.

29. Health effects of secondhand smoke and economic impact of smoke-free bar and restaurant ordinances. Marlborough Community Forum. Marlborough, MA, May 13, 1998.

30. Course coordinator, "Clean Indoor Air Policies," Tobacco Control Summer Institute, Albuquerque, NM, July 27-31, 1998.

31. Health effects of secondhand smoke and economic impact of smoke-free bar and restaurant ordinances. Holyoke Board of Health, Holyoke, MA, July 7, 1998.

32. Siegel M. Ethical implications of a global tobacco settlement. American Public Health Association annual meeting. Washington, DC, November 16, 1998.

33. Siegel M, Carfano E. Teaching public health students how to produce television commercials: Development of an innovative course in health communication. American Public Health Association annual meeting. Washington, DC, November 17, 1998.

34. The impact of tobacco promotions on adolescent smoking: results of a longitudinal study in Massachusetts. Presented at Robert Wood Johnson Foundation Substance Abuse Policy Research Program Annual Meeting. Charleston, SC, December 10, 1998.

35. Biener L, Siegel M. Tobacco product promotions and adolescent smoking: more evidence of a causal relationship (poster). Annual conference of the Society for Research on Nicotine and Tobacco (SRNT). San Diego, CA, March 5-7, 1999.

36. Rigotti NA, Siegel M, Biener L. The effect of local tobacco sales laws on adolescent smoking initiation (poster). Annual conference of the Society for Research on Nicotine and Tobacco (SRNT). San Diego, CA, March 5-7, 1999.

37. Marketing public health: Strategies to promote social change. Workshop leader and presenter. Annual conference of the Massachusetts Prevention Centers. Marlboro, MA, March 24, 1999.

38. The effects of the Massachusetts anti-tobacco media campaign on youth tobacco use. Cancer Prevention and Control Grand Rounds. Boston University School of Medicine. May 4, 1999.

39. King C, Siegel M. Adolescent exposure to cigarette advertising in magazines: An evaluation of brand-specific advertising in relation to youth readership. INFORMS (Institute for Operations Research and the Management Sciences) Marketing Science Conference. Syracuse, NY, May 22, 1999.

40. Marketing public health: Strategies to promote social change. Plenary session address. Annual conference of the New York State Public Health Association / New York State Association of County Health Officials. Cooperstown, NY, May 25, 1999.

41. Siegel M. The health effects of secondhand smoke (guest lecture). Tobacco Use Prevention Summer Institute. Atlanta, GA, July 26, 1999.

42. Siegel M, Heaphy D. Bringing television cameras and the internet into the public health classroom: Teaching students to develop a mass media campaign. American Public Health Association Annual Meeting. Chicago, IL, November 9, 1999.

43. Siegel M. Exposure to cigarette advertising in magazines and its impact on youth smoking (poster). American Public Health Association Annual Meeting. Chicago, IL, November 9, 1999.

44. Siegel M. The impact of anti-smoking media campaigns on smoking initiation. American Public Health Association Annual Meeting. Chicago, IL, November 9, 1999.

45. Smoking and fast cars: the use of motor sports sponsorship as a promotional tool. Cancer Prevention and Control Grand Rounds. Boston University School of Medicine. November 7, 2000.

46. Circumventing the cigarette television advertising ban: a review of tobacco industry sponsorship of motor sports events. Harvard University Tobacco Control Working Group. February 6, 2001.

47. Siegel M, King C. Adolescents and cigarette advertising in popular magazines: The fifteen percent rule and beyond (panel presentation and discussion). Marketing and Public Policy Conference. June 1, 2001, Washington, DC.

48. Siegel M. The descriptive epidemiology of local restaurant smoking regulations in Massachusetts: Implications for studying the effectiveness of clean indoor air policies. National Cancer Institute State and Community Tobacco Control Interventions Research Grantees Meeting. January 29, 2002, San Diego, CA.

49. Siegel M. Policies to protect restaurant workers from secondhand smoke (guest lecture). Tobacco Use Prevention Summer Institute. Kansas City, MO, July 11, 2002.

50. King C, Siegel M. Measuring youth exposure to cigarette advertising in magazines post-Master Settlement Agreement. American Public Health Association Annual Meeting. Philadelphia, PA, November 11, 2002.

51. Albers AB, Siegel M. Development and validation of a coding system to assess the strength of local clean indoor air policies. National Tobacco Control Conference. San Francisco, CA, November 19, 2002.
52. Siegel M. Banning smoking in bars and restaurants: Protecting the public's health or infringing on civil liberties? Food for Thought Lecture Series, Boston University. December 3, 2002.

53. Siegel M. Smoking in bars: the last frontier? Cancer Prevention and Control Grand Rounds. Boston University School of Medicine. May 13, 2003.

54. Skeer M, Siegel M. Boston's smoking ban: chaos or compliance? Research Lunch Series. Boston University School of Public Health. September 17, 2003.

55. Siegel M, Albers AB, Skeer M. Effect of local restaurant smoking regulations on secondhand smoke exposure and social norms regarding smoking among youths. American Public Health Association Annual Meeting. San Francisco, CA, November 18, 2003.

56. Siegel M, Albers AB, Skeer M. Impact of local restaurant and bar regulations on adult exposure to

secondhand smoke and social norms related to smoking. American Public Health Association Annual Meeting. San Francisco, CA, November 18, 2003.

57. Siegel M, Skeer M. Boston's smoking ban: chaos or compliance? Harvard University Tobacco Control Working Group. December 3, 2003.

58. Siegel M, Godshall WT, Cummings KM, Blum A. FDA regulation of tobacco: Opportunity or diversion for the next decade? (panel presentation). National Conference on Tobacco or Health, Chicago, IL, May 4, 2005.

59. Siegel M. News for a Change (media advocacy training). American Cancer Society, Massachusetts Chapter. Framingham, MA, August 24, 2005.

60. Siegel M. Media advocacy training. Massachusetts Department of Public Health. Boylston, MA, April 21, 2006.

61. Siegel M. Media advocacy training. Massachusetts Department of Public Health. Boston, MA, June 20, 2006.

62. Siegel M. Media advocacy training. Massachusetts Department of Public Health. Boston, MA, August 1, 2006.

63. Fortunato EK, Siegel M. Framing public health as an institution: a case study (poster presentation). American Public Health Association Annual Meeting. Boston, MA, November 7, 2006.

64. Siegel M. Taking it to the House: How the Tobacco Companies Play You for Profit. Reduce the Use Night. Natick High School, Natick, MA, November 15, 2006.

65. Siegel M. Science, Communication and Scientific Integrity: The Example of Secondhand Smoke, and Balancing Health and Autonomy in Public Health Policy: The Example of Car Smoking Bans. Freedom, Tolerance, and Civil Society Conference (sponsored by Institute for Humane Studies, George Mason University). Simmons College, Boston, MA, June 20, 2007.

66. Siegel M. Tobacco Advertising and Health Disparities. STOMP (Stomp Tobacco Out Mass People) Symposium. Zoo New England, Boston, MA, May 15, 2007.

67. Siegel M. Science, Communication and Scientific Integrity: The Example of Secondhand Smoke, and Balancing Health and Autonomy in Public Health Policy: The Example of Car Smoking Bans. Freedom, Tolerance, and Civil Society Conference (sponsored by Institute for Humane Studies, George Mason University). Simmons College, Boston, MA, June 17, 2008.

68. Siegel M, King C, Ross C, Ostroff J, Jernigan DH. Alcohol Advertising in Magazines: Are Youths

Disproportionately Exposed? American Public Health Association Annual Meeting. San Diego, CA, October 27, 2008.

69. Siegel M. Top 10 Myths About Health Care Reform. Lifetime Learning – The Dr. George Altman World Affairs and Politics Lecture Series. Newton, MA, April 7, 2010.

70. Siegel M. Evidence-Based Science and Regulation of Tobacco Products. Tobacco Merchants Association Annual Meeting and Conference. Williamsburg, VA: May 25, 2010.

71. Siegel M, DeJong W, Fortunato EK, Johnson A, DiLoreto J, Ross C, Heeren T, Naimi TS. Descriptive epidemiology of brand-specific alcohol use among underage youths. American Public Health Association Annual Meeting. Denver, CO, November 9, 2010.

72. Siegel M. Underage drinking and the media. Norfolk District Attorney Underage Drinking Prevention Conference, Wrentham, MA, September 20, 2011.

73. Siegel M. Can modified risk tobacco products serve the public's health? Two barriers stand in the way. Tobacco Regulation and Litigation Conference. Food and Drug Law Institute. Washington, DC, December 5, 2011.

74. Siegel M. Top ten myths regarding harmful and potentially harmful tobacco constituents. Tobacco Merchants Association National Meeting and Conference, Williamsburg, VA: May 22, 2012.

75. Siegel M. Top two myths regarding the modified risk tobacco products provisions of the Tobacco Act. Tobacco Merchants Association National Meeting, Williamsburg, VA: May 22, 2012.

76. Siegel M, Ayers AJ, DeJong W, Naimi T, Jernigan DH. Differences in brand-specific alcohol consumption among youth by age, gender, race, and socioeconomic status – United States, 2011. Annual meeting of the American Public Health Association, San Francisco, CA: October 31, 2012.

77. Siegel M. Keynote address: The nexus of science and law in tobacco control policy. The Future of Global Tobacco Control: Current Constitutional and Treaty-Based Challenges. The American Journal of Law & Medicine 2013 Symposium. Boston University School of Law, January 25, 2013.

78. Siegel M. Alcohol, tobacco, and firearms: from science to policy. Department of Pediatrics Grand Rounds. Boston University Medical Center. January 31, 2013.

79. Siegel M, Naimi TS. From tobacco to alcohol: the need for a brand-specific research agenda. Alcohol Policy 16. Washington, DC, April 3, 2013.

80. Siegel M. Consumption of alcohol by brand among underage youth and adults in the United States. Alcohol Policy 16. Washington, DC, April 4, 2013.

81. Siegel M, Naimi TS. Brand-specific alcohol prices: a new surveillance method and policy implications. Alcohol Policy 16. Washington, DC, April 5, 2013.

82. Siegel M. Interrogation research by Yale medical school faculty members: ethical and human subjects protection concerns. Presented at: Knowledge and Power: A conversation about the Military and National Security in Academia. Yale University, New Haven, CT, April 15, 2013.

83. Siegel M. Do guns kill people or do people kill people? Medicine and Public Health Association at Boston University panel on gun control. Boston University Medical Center, April 25, 2013.

84. Siegel M. Success rates for nicotine replacement therapy. Tobacco Merchants Association National Meeting and Conference, Williamsburg, VA: May 16, 2013.

85. Siegel M. Medicinal and lifestyle nicotine products: what works? Tobacco Merchants Association National Meeting and Conference, Williamsburg, VA: May 17, 2013.

86. Siegel M. Rebel with a cause: harnessing the core values of adolescence to prevent substance abuse. Department of Public Health School Health Conference, Boston, MA: October 1, 2013.

87. Siegel M. Electronic cigarettes: youth use. Tobacco Merchants Association Meeting: FDA Regulation of Electronic Cigarettes, Leesburg, VA: October 30, 2013.

88. Siegel M. What's in a brand? How an understanding of what brands youth are drinking can help identify effective interventions. 9th Annual New England School Safety Conference, Norwood, MA: April 8, 2014.

89. Siegel M. The safety of electronic cigarettes: What do we know in 2014? Tobacco Merchants Association National Meeting and Conference, Williamsburg, VA: May 22, 2014.

90. Siegel M. Should physicians recommend electronic cigarettes for their smoking patients (plenary debate)? Annual conference of the Association for Medical Education and Research in Substance Abuse (AMERSA), San Francisco, CA: November 7, 2014.

91. Siegel M. Behavioral Study of Cigarette and Tobacco Substitution. E-Vapor Research Collaborative Funding Conference, Leesburg, VA: December 9, 2014.

92. Siegel M. Should medical providers recommend e-cigarettes to their patients as a smoking cessation tool? Pearls for Practice: The Fourth Annual MASAM (Massachusetts chapter of the American Society of Addiction Medicine) Addiction Medicine Risk Management Course for All Providers, Waltham, MA: June 26, 2015.

93. Siegel M. Electronic cigarettes and harm reduction (invited panel). Annual Drug Policy Reform Conference, Washington, DC: November 21, 2015.

94. Siegel M. Electronic cigarettes: Why we can't handle the truth. Responsible Retailing Forum Annual Meeting, Boston, MA: April 20, 2016.

95. Siegel M. Electronic cigarettes: Why we can't handle the truth. National Tobacco Harm Reduction Conference, New York, NY: April 21, 2016 (via Skype).

96. Siegel M. Forced to lie: The marketing implications of the FDA's deeming regulations for electronic cigarettes. Regulations for E-Cigarettes national conference, Alexandria, VA: December 7, 2016.

97. Siegel M. Impact of state concealed carry permitting legislation on homicide rates. American State Legislators for Gun Violence Prevention Fourth Annual Policy Summit, Boston, MA: August 7, 2017.

98. Siegel M. Breaking the gridlock in the firearm debate: Is there common ground? Rhett Talks program. Boston University, September 19, 2017.

99. Siegel M. Industry Expert Theater: A Robert Wood Johnson Foundation Evidence for Action Program grantee viewpoint. Annual Meeting of the American Public Health Association, Atlanta, GA, November 7, 2017.

100. Siegel M, Pahn M. Development of a comprehensive state firearm law database. Annual Meeting of the American Public Health Association, Atlanta, GA, November 7, 2017.

101. Siegel M. State laws to reduce firearm-related intimate partner violence: Do they work, and does enforcement matter? Annual Meeting of the American Public Health Association, Atlanta, GA, November 8, 2017.

102. Siegel M. Exposure to brand-specific alcohol advertising among underage youth: Is the alcohol industry's self-regulatory code effective? Annual Meeting of the American Public Health Association, Atlanta, GA, November 8, 2017.

103. Siegel M, Knopov A. The impact of state-level firearm laws on homicide rates by race/ethnicity. American Society of Criminology Annual Conference, Philadelphia, PA, November 17, 2017.

104. Siegel M. Precision dissemination: 10 critical steps in 10 minutes. Chandler, AZ: Robert Wood Johnson Foundation Sharing Knowledge Conference, March 9, 2018.

105. Siegel M. Reducing firearm violence: How research can play a role. Boston University Management Town Meeting, Boston, MA, March 12, 2018.

106. Siegel M, Knopov A. Differential impact of state firearm laws on Black and White populations.

Public Health Law Conference, October 5, 2018.

107. Siegel M. Do alcohol companies target youth with their magazine advertisements? Public Health Law Conference, October 6, 2018.

108. Siegel M, Knopov A. Impact of state firearm laws on homicide rates among the Black and White populations in the United States, 1991-2016. American Public Health Association Annual Meeting, San Diego, CA, November 12, 2018.

109. Mesic A, Knopov A, Siegel M. Relationship between structural racism and Black-White disparities in fatal police shootings at the state level and the city level. American Public Health Association Annual Meeting, San Diego, CA, November 12, 2018.

110. Knopov A, Mesic A, Siegel M. Role of racial residential segregation in Black-White disparities in firearm homicide at the state level in the United States, 1991-2016. American Public Health Association Annual Meeting, San Diego, CA, November 12, 2018.

111. Boine C, Knopov A, Siegel M. Relation between homicides and firearm culture indicators. American Public Health Association Annual Meeting, San Diego, CA, November 12, 2018.

112. Cronin SW, Siegel M, Solomon B, Knopov A, Rothman, EF, Xuan Z, Hemenway D. The impact of state firearm laws on homicide rates in large urban cities and areas outside of large cities in the United States, 1991-2016. American Society of Criminology Annual Meeting, Atlanta, GA, November 15, 2018.

113. Siegel M. What does it mean to say that firearm violence is a public health issue? Robert Wood Johnson Foundation Sharing Knowledge Conference, Houston, TX, March 8, 2019.

114. Neufeld M, Siegel M, Sanchez S. Physician organizations' role in Political Action Committee funds, 2018. American Public Health Association Annual Meeting, November 4, 2019, Philadelphia, PA.

115. Siegel M. The relationship between racial segregation and Black-White disparities in fatal police shootings at the city level. American Society of Criminology Annual Meeting, November 15, 2019, San Francisco, CA.

Testimony Given in Litigation

Trial Testimony

- Norma R. Broin, et al v. Philip Morris Companies, Inc., et al, Case No. 91-49738 CA (22)

(Circuit Court of the 11th Judicial Circuit, Dade County, Florida)
Attorney: Stanley Rosenblatt

- Howard A. Engle, et al v. Philip Morris Companies, Inc. et al, Case No. 94-08273 CA (22)
(Circuit Court of the 11th Judicial Circuit, Dade County, Florida): Phases I, II, and III and Punitive Damages phase
Attorney: Stanley Rosenblatt
- Dawn Apostolou v. The American Tobacco Company et al., Index No. 34734/00
(Supreme Court of the State of New York, County of Kings): Phases I and II
Attorney: Michael London
- People of the State of California, ex rel. Bill Lockyer, Attorney General of the State of California v. R.J. Reynolds Tobacco Company
(Superior Court of California, County of San Diego)
Attorney: Alan Lieberman
- Julien Longden and Sheila Longden v. Philip Morris, Inc., et al., Docket No. 00-C-462
(Superior Court of New Hampshire, Hillsborough)
Attorney: Chuck Douglas
- Koenig vs. Wyeth, Inc., et al., Case No. 02-18165 CA 32
(Circuit Court of the 11th Judicial Circuit, Dade County, Florida)
Attorney: Stanley Rosenblatt
- Re: E.I. DuPont De Nemours and Company C8 Personal Injury Litigation, Case No. 2:13-MD-2433
(United States District Court, Southern District of Ohio, Columbus, Ohio)
Attorney: Mike Papantonio [BARTLETT] - 2015
- Re: E.I. DuPont De Nemours and Company C8 Personal Injury Litigation, Case No. 2:13-MD-2433
(United States District Court, Southern District of Ohio, Columbus, Ohio)
Attorney: Mike Papantonio [FREEMAN] - 2016
- Re: E.I. DuPont De Nemours and Company C8 Personal Injury Litigation, Case No. 2:13-MD-2433
(United States District Court, Southern District of Ohio, Columbus, Ohio)
Attorney: Gary Douglas [VIGNERON] – 2016
- Re: E.I. DuPont De Nemours and Company C8 Personal Injury Litigation, Case No. 2:13-MD-2433
(United States District Court, Southern District of Ohio, Columbus, Ohio)
Attorney: Gary Douglas [MOODY] - 2017

Hearing Testimony

- Vapor Technology Association, Ian Devine, and Devine Enterprise Inc., vs. Charlie Baker (Massachusetts Superior Court, Suffolk County)
Attorney: Joe Terry - 2019

Depositions Taken

- Norma R. Broin, et al v. Philip Morris Companies, Inc., et al, Case No. 91-49738 CA (22)
(Circuit Court of the 11th Judicial Circuit, Dade County, Florida)

Attorney: Stanley Rosenblatt

- Howard A. Engle, et al v. Philip Morris Companies, Inc. et al, Case No. 94-08273 CA (22)
  (Circuit Court of the 11th Judicial Circuit, Dade County, Florida): Phases I, II, and III and punitive damages phase
  Attorney: Stanley Rosenblatt
- Antonio Badillo, et al, v. The American Tobacco Company, Inc., et al, CV-N-97-00573-ECR(RAM)
  (United States District Court, District of Nevada)
  and
  Joseph Avallone, et al, v. The American Tobacco Company, Inc., et al, Docket No. L-4883-98, Case Code 241
  (Superior Court of New Jersey, Middlesex County)
  Attorney: Perry Nicosia
- Robert Murphy v. The American Tobacco Company, Inc., et al, CV-S-98-00021-HDM(RJR)
  (United States District Court, District of Nevada)
  Attorney: Perry Nicosia
- People of the State of California, ex rel. Bill Lockyer, Attorney General of the State of California v. R.J. Reynolds Tobacco Company
  (Superior Court of California, County of San Diego)
  Attorney: Alan Lieberman
- Julien Longden and Sheila Longden v. Philip Morris, Inc., et al., Docket No. 00-C-462
  (Superior Court of New Hampshire, Hillsborough)
  Attorney: Chuck Douglas
- Koenig vs. Wyeth, Inc., et al., Case No. 02-18165 CA 32
  (Circuit Court of the 11th Judicial Circuit, Dade County, Florida)
  Attorney: Stanley Rosenblatt
- Re: E.I. DuPont De Nemours and Company C8 Personal Injury Litigation, Case No. 2:13-MD-2433
  (United States District Court, Southern District of Ohio, Columbus, Ohio)
  Attorneys: Robert Billott, Mike Papantonio, Gary Douglas

- *Neal v. Monsanto*. Co., No. 1722-CC10773. (Mo. Cir. Ct. St. Louis. City)
  Attorney: Robin Greenwald

- *Winston v. Monsanto*. Co., (Mo. Cir. Ct. St. Louis. City)
  Attorney: Robin Greenwald

Amicus Briefs Submitted

Smoking Everywhere, Inc., and Sottera, Inc., D/B/A NJOY v. Food and Drug Administration, et al. United States Court of Appeals for the District of Columbia Circuit. Submitted on July 8, 2010.

Nicopure Labs, LLC, et al., v. U.S. Food and Drug Administration, et al. United States District Court for the District of Columbia. Submitted on August 8, 2016.

Nicopure Labs, LLC, Right to Be Smoke Free Coalition, et al., v. Food and Drug Administration, et al. Submitted on February 20, 2018.

George K. Young, Jr. v. State of Hawaii, et al. United States Court of Appeals for the Ninth Circuit. Submitted on June 4, 2020.

Congressional Testimony

Hearing on Legislation to Reverse the Youth Tobacco Epidemic. Subcommittee on Health of the House Committee on Energy and Commerce, Washington, DC, October 16, 2019.

Extramural Grant Funding

Title and Years of Grant Funding	Granting Agency	Amount/Duration	Role
Cigarette Advertising in Magazines and Youth Smoking Behavior (1997-1998)	Massachusetts Department of Public Health (DPH)	$64,000 (1 year)	PI
Influence of Tobacco Marketing and Counter-advertising on Smoking Initiation among Youth (1997-1999)	Robert Wood Johnson Foundation (RWJF)	$200,000 (2 years)	PI
The Tobacco Industry Sponsorship Research Project (1998-2001)	American Cancer Society (ACS)	$251,000 (3 years)	PI
Denormalizing Smoking via Policy and Media Interventions (2000-2004)	NIH/NCI	$4,139,027 (4 years)	Co-PI
Protecting Workers and the Public From Secondhand Smoke: The Impact Of Clean Indoor Air Policies on Secondhand Smoke Exposure and Smoking Behavior (2002-2005)	Flight Attendant Medical Research Institute (FAMRI)	$651,000 (3 years)	PI
Tobacco Use Trajectories Amid Fluctuating State Program Budgets (2004-2007)	NIH/NCI	$1,771,053 (3 years)	Co-PI

*Note: from 2008-2010, I served as concentration director for the Social and Behavioral Sciences Department and taught two classes per semester which replaced my research funding for that period

Alcohol Brand Research among Underage Drinkers (2011-2015)	NIH/NIAAA	$1,570,267 (4 years)	PI
Building a Culture of Health around Firearms: The Relationship between Social Gun Culture, Gun Ownership, Firearm Policy, and Firearm Violence (2016-2017)	Robert Wood Johnson Foundation (RWJF)	$486,426 (1.5 years)	PI

The Impact of State-Level Firearms Laws on Homicide Rates by Race/Ethnicity (2017-2019)	National Institute of Justice (NIJ)	$610,000 (3 years)	PI
Identifying Shared Values to Support An Inclusive Culture of Health around Firearms: What Communication Messages Work? (2018-2021)	Robert Wood Johnson Foundation (RWJF)	$599,413 (3 years)	PI